Audit and Risk Assurance Committee Agenda

Date 12 February 2019
Time 10:00 – 16:30
Venue Boardrooms 1 / 2, 2nd floor, 151 Buckingham Palace Road

Private Members Session:

ARAC Members private session (9:45 – 10:00)
Confidential meeting with Internal and External Auditors (10:00 – 10:30)

Meeting:

Main ARAC meeting (10:30 – 13:00)

Lunch:

Lunch (13:00 – 13:30)

Training:

Improving Audit Committee Effectiveness training (13:30 to 16:30)

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of Meeting 23 October 2018	(AUD 27/18)
4.	Matters arising from 23 October 2018 and forward plan	(AUD 28/18)
5.	ARAC Chair's Update	Oral
	External Audit	
6.	NAO update on 1st week of interim audit	Oral
	Internal Audit (Confidential)	
7.	Internal Audit update	(AUD 29/18)
	• Records Management	Annex A
	• GDPR Audit	
	• *Cyber Security follow-up audit (requested 23 Oct)*	

	• Review and approval of the draft Internal Audit Plan 2019/20	Oral
	Audit Tracking	
8.	Audit Tracker Update	(AUD 30/18)
	Risk Update	
9.	Risk Update	(AUD 31/18)
	• HTA Strategic Risk Register	Annex A
10.	Cyber Security & IT Resourcing	Oral
11.	Third Party Agreements	(AUD 32/18)
	Exploration of Risk Areas – Transformation	
12.	Exploration of Risk Area – Assurance associated with preparedness for the transformation programme (a collaborative exercise between Executive and ARAC Members	(AUD 33/18)
	Policy / Procedures updates	
13.	*Policy and procedure update*	(AUD 34/18)
	Annex A: Schedule of Policies	Annex A
	Annex B: Anti-Fraud policy	Annex B
	Annex C: Whistleblowing policy	Annex c
14.	Review of the Audit & Risk Assurance Committee's performance including Members' skills and training	(Oral)
15.	Review of Gifts and Hospitality register	(AUD 35/18)
	• Gifts and Hospitality Register	Annex A
	Regular reporting and updates	
16.	Reports on grievances, disputes, complaints, fraud and other information	Oral
17.	Topics for future risk discussions	Discussion
18.	Topics for future ARAC training	Discussion
	Any other business	

Meeting close

HTA Human Tissue Authority

Minutes of the Audit Risk and Assurance Committee

Date	23 October 2018	**Paper**	(AUD 27/18)
Venue	Boardroom 1&2 151 Buckingham Palace Road, SW1W 9SZ		
Protective Marking	OFFICIAL		

Present	
Members Amanda Gibbon (Chair) Glenn Houston Prof. Andrew (Andy) Hall Dr. Stuart Dollow William (Bill) Horne	**In attendance** Allan Marriott-Smith (Chief Executive) Richard Sydee (Director of Resources) Hazel Lofty (Director of Regulatory Development) Nicolette Harrison (Director of Regulatory Delivery) (by Skype) Morounke Akingbola (Head of Finance and Governance) Dr. Amy Thomas (Head of Regulatory Development) (Items 12, 13) Diane Galbraith (Head of HR) (Item 14) Lesley Campbell (Temp Board Secretary)
Apologies Jacky Cooper (Department of Health and Social Care) Ann Beasley (former Director General of Finance and Corporate Services at Ministry of Justice) David Thomson (Head of Business Technology)	**External Attendees** Jeremy Nolan (Government Internal Audit Agency) Tony Stanley (Government Internal Audit Agency) Jill Hearne (National Audit Office) Sarah Edwards (National Audit Office)

Item	Title
Item 1	**Welcome and apologies**
	1. Amanda Gibbon (the Chair) welcomed Audit and Risk Assurance Committee (ARAC) Members and attendees to the meeting. 2. The Chair welcomed Hazel Lofty (Director of Regulatory Development) and Nicolette Harrison (Director of Regulatory Delivery) to their first ARAC meeting since taking up their new positions, and Lesley Campbell (temporary Board Secretary). The Chair advised that Dr. Amy Thomas (Head of Development) would join the meeting in relation to items 12 and 13 [ARAC Papers (AUD 21/18) and (AUD 22/18)], and to provide an oral update on work related to the UK's exit from the European Union. 3. The Chair advised the Committee that she had received apologies for absence from Jacky Cooper from the Department of Health and Social Care (DHSC), David Thomson, Dan Howard and Ann Beasley. 4. The Chair informed the Committee that the HTA Audit Planning Report 2018/19 Financial Statement Audit was not included in the agenda, but would be presented after item 7.
Item 2	**Declarations of interest – Oral**
	3. The Chair asked Members to declare any personal or pecuniary interests in regard to the meeting's agenda; none were declared.
Item 3	**Minutes of 19 June 2018 – (AUD 14/18)**
	4. The minutes of the meeting of 19 June 2018 were agreed as an accurate record of that meeting.
Item 4	**Matters arising – (AUD 15/18)**
	5. The Chair advised members of the Committee that a copy of the matters arising and forward plan had been circulated [ARAC Paper (AUD 15/18)]. 6. The Chair noted that the actions arising from the meeting on 19 June 2018 were resolved, are noted on the forward plan or would be addressed within the relevant agenda items of the meeting. Updates were provided on the following actions which are now closed.

7. Action 1: SD provided an update on contact with the National Institute for Health and Care Excellence (NICE)

8. Action 2: Richard Sydee provided members with an update on access to the Work app.

9. Action 3: The HTA's Data Protection Officer provided his apologies for this meeting and hoped to be able to attend a future meeting.

10. Action 5: Richard Sydee provided an update on the notification of access proforma. This has highlighted the need for an audit of existing permissions prior to finalising and roll out of the forms.

11. Action 6: The Chair of the HTA met with the Minister in July. An update was provided to Members at the Strategy Away Day in September.

12. Action 13: the Executive confirmed that the compulsory eLearning modules incorporate a short test to demonstrate understanding. Records of completion are maintained by HR.

13. The Chair requested an update on a number of issues arising from previous meetings:

    - Rent update – the HTA continues to accrue for the full amount until such times as the matter is resolved.

    - Recruitment – the Executive provided an update on recruitment to the Head of Planning and Performance role (previously advertised as Head of Operations)

    - 2018/19 Grant-in-Aid (GIA) – RS provided clarification on the current position and is awaiting confirmation from DHSC in relation to ring-fenced RDEL; this funding has not been included in the budget.

    - HR software migration – subject to resolving outstanding security questions, this is scheduled for Q4.

    - IT contract tender – RS provided an update on the outcome of the tender process. No suitable submissions were received. Having demonstrated suitable value for money, the contract

	with the current provider will be extended for a fixed period subject to the necessary variations being agreed. • Loss of devices as a standing item will be covered under the Cyber Security update at item 9. 14. The Chair asked members whether there were any other matters arising. No further matters were identified. **Action 1: RS to invite Dan Howard, the HTA Data Protection Officer, to attend a future ARAC meeting**
Item 5	**ARAC Chair's update – Oral**
	15. Dates for 2019/20 ARAC meetings have now been agreed and circulated to Committee members. 16. The Chair is awaiting details of the National Audit Office (NAO) Audit Committee Chairs' event and will update the Committee once further information is available. 17. The Chair informed the Committee that Clare Wend-Hansen, a Regulation Manager, had been appointed as the new Staff Champion. The Chair will be meeting with Clare in due course. 18. The Chair informed the Committee that she had spoken with Jeremy Nolan (GIAA) in advance of today's meeting. 19. The Chair reminded the Committee that she would be presenting to HTA staff on the role of ARAC following the meeting, and that members of the Committee were welcome to attend and participate in the Q & A session.
Item 6	**Internal Audit update – (AUD 16/18)**
	20. The Committee were provided with an update on progress with the agreed 2018/19 Internal Audit Plan. The Chair noted that the reference to 'Payroll and expenses' on the agenda under this item was included in error and should be disregarded.

	21. Tony Stanley presented an overview of the recent advisory review on Stakeholder Engagement. Committee members discussed the content of the Audit report [ARAC paper (AUD 16/18) Annex A] and commended staff on the positive outcomes. 22. Committee members noted the suggestions in the report to further strengthen the HTA's stakeholder engagement including improvements to the website, social media and wider engagement through other organisations, some of which is already planned. 23. Committee members also expressed the importance of streamlining engagement with other regulatory authorities and ensuring that there is proactive regional outreach, in particular with the devolved administrations. 24. Jeremy Nolan highlighted that although the review was advisory, members of the Committee should take positive assurance from the review findings. 25. Jeremy Nolan advised the Committee that the next audit would review records management. The outcomes of the review along with the cyber security follow up will be reported at the February ARAC meeting.
Item 7	**Audit Tracker update – (AUD 17/18)**
	26. Morounke Akingbola presented an update on progress made in response to external and internal audit recommendations as set out in [ARAC Paper (AUD 17/18)]. 27. The Committee approved the removal of the completed recommendations relating to Corporate Governance and Financial Controls from the tracker. 28. The Committee reviewed progress towards completing the actions from the Cyber Security Audit, a number of which have been delayed. Members emphasised the need to identify realistic target dates when planning actions. 29. The Committee raised concerns about the demand on IT resource on a number of fronts and received assurance that this was a matter already identified and under consideration by SMT as part of strategic planning. It was agreed that Members would be provided

	with an update on IT resourcing at the 12 February ARAC meeting. 30. The Committee were advised that Internal Audit would be conducting a follow up review on cyber security, which is planned for January 2019. An update will be provided at the 12 February ARAC meeting. **Action 2: Completed items from the Corporate Governance and Financial Control audits to be removed from the tracker.** **Action 3: The Committee to receive an update on IT resourcing at the 12 February 2019 ARAC meeting.** **Action 4: Internal Audit to conduct follow up review on Cyber Security and provide an update at the 12 February 2019 ARAC meeting.**
	Additional agenda item – Audit Planning Report on the 2018/19 Financial Statement Audit
	31. Jill Hearne presented an overview of the National Audit Office's (NAO) proposed approach to the 2018/19 Financial Statement Audit. Members were taken through the key audit risks, materiality levels, timetable and proposed fee. 32. Members were provided with an update on the NAO team structure, with Jill taking over from Sarah Edwards. The Committee thanked Sarah for her work with the HTA. 33. Members were advised that a planning meeting with Morounke Akingbola and Richard Sydee had been undertaken. No additional significant risks have been identified. In addition to the standard approach the audit will focus on two areas: CRM upgrade and EU Exit. The latter has been flagged for inclusion in all audits. 34. The Chair asked for assurance that the timetable was reasonable, given availability of staff resource. Richard Sydee advised that there will be more detailed internal planning for production of the annual report. An interim audit will commence in February 2019. 35. The Committee thanked the NAO for a clear plan, that had been well put together.

	36. Members of the Committee agreed to the NAO's approach to the 2018/19 Financial Statement Audit.
Item 8	**Risk update – (AUD 18/18)**
	37. Richard Sydee presented an update on the strategic risks and mitigations set out within the latest iteration of the HTA Strategic Risk Register (SRR) [ARAC Paper (AUD 18/18) – Annex A]. The Committee reviewed the HTA's Operational Risk Register (ORR) which had been included within the meeting papers [ARAC Paper (AUD 18/18) – Annex B]. 38. The Committee was advised that there had been no substantial change to the risks presented since the June meeting, but that Members should note the upward pressure on Risk 4: *failure to utilise our capabilities effectively* which reflects the challenges and resource implications involved in training new staff. 39. Members were advised that in relation to Risk three: *failure to manage expectations of regulation*, the Executive were monitoring developments with both deemed consent legislation and EU Exit closely. 40. Allan Marriott-Smith advised that a new strategic risk relating to the planned organisational transformation work was currently being drafted, and would include a number of areas raised by the Committee. 41. The Committee discussed the format and the content of the Risk Registers more generally, and whether key risks were adequately presented for the purposes of ARAC. The SMT advised that similar discussions had taken place internally, but noted that it would require significant work to replace the current process. 42. Members agreed to give further consideration to ARAC's requirements in relation to gaining assurance on how risks are recorded and managed, and how they can be most effectively presented for consideration at meetings. 43. Jeremy Nolan agreed to assist in providing training for ARAC Members at a future ARAC meeting.

	Action 5: Jeremy Nolan to facilitate further discussion/training for ARAC Members on risk updates at a future ARAC meeting.
Item 9	**Cyber security – (Oral)**
	44. This is now a standing agenda item as agreed at the ARAC meeting on 19 June 2018. 45. No further security or personal data breaches were reported other than the incident reported to ARAC on 9 July 2018.
Item 10	**General Data Protection Regulation – (AUD 19/18)**
	46. Richard Sydee presented the Committee with an update on the HTA's compliance with the General Data Protection Regulation [ARAC Paper (AUD 19/18)]. 47. Members were advised that, although good progress has been made in achieving a defensible position, there remain a number of pieces of work outstanding primarily due to resource availability. These have been assessed as low risk and are anticipated to be complete by the end of the business year, subject to a more detailed planning exercise. 48. Whilst recognising current resource constraints, Members expressed concern at delays in completing the outstanding actions. Members were provided with assurance that all personal data was held securely, and therefore any risk of breach was considered to be low, however the SMT recognised that further work required prioritisation. Members requested a further update in advance of the February 12th ARAC meeting. 49. Members requested that Authority Members receive training on their obligations. Richard Sydee proposed that this was combined with Cyber Security training. **Action 6: Richard Sydee to provide ARAC Members with an update on GDPR implementation progress ahead of the February ARAC meeting.**

	Action 7: **Training on GDPR obligations to be added to the Authority forward plan to coincide with Cyber Security training.**
Item 11	**Critical Incident Response Plan – Update - (AUD 20/18)**
	50. The Chair reminded Members that they had requested an updated version of the critical incident response plan (CIRP) following the ARAC meeting on 19 June 2018. Members considered the content of the update on the Critical Incident Response Plan which had been provided and agreed that they should review the revised plan in its entirety. 51. The Chair requested that the revised Critical Incident Response Plan be circulated by email following the meeting and asked Members to provide any comments on it by email to Richard Sydee. **Action 8: Electronic version of the updated CIRP to be emailed to Members.** **Action 9: Members to provide comments on the updated CIRP to Richard Sydee via email.**
Item 12	**Oversight Strategy for Third Party Agreements – (AUD 21/18)**
	52. Dr Amy Thomas provided Members with an update on proposals to improve oversight of activity carried out by third parties in the Human Application (HA) sector [ARAC Paper (AUD 21/18)]. 53. Members sought clarification on any unlicensed activity highlighted by the data collection exercise and also the expectations of establishments with respect to third party agreement oversight. Amy Thomas informed the Committee that she was not aware of any unlicensed activity, and that the requirements relating to third party agreements (including HTA oversight) were clearly set out in the HTA's Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment and were routinely covered by inspections. 54. Members noted the content of the report. An update will be brought to the February 2019 meeting.

Item 13	Better Use of Data through the 2017/18 Safety KPI Report (AUD 22/18)
	55. Dr Amy Thomas provided Members with an overview of the data collated through the 2017/18 business year as part of a safety KPI [ARAC Paper (AUD 22/18)]. 56. Members were asked to consider whether the data collected through the safety KPI work provides sufficient assurance that the HTA is monitoring its activities, and is using this information to evaluate issues that may affect patient safety and public confidence. 57. Members discussed the content of the report and agreed it was useful and interesting for ARAC to review, and provided the requested assurance. Members also agreed that the report was not suitable for publication in its current form, but that themes should be selected for feedback to establishments and also to inform compliance updates. 58. The Chair suggested that the work could be used to further develop the Delivery Report to the Authority. Nicolette Harrison agreed that the safety KPI work demonstrates the value of analysing our data holdings and that we would continue to build further capability to achieve this more systematically. 59. Members requested that a more detailed review of critical shortfalls should be provided to the Authority. 60. Members thanked the team for their work in compiling the report. **Action 10: ANH to consider the feasibility of including some of the data from the safety KPI work into the Delivery Report.** **Action 11: The Executive to consider adding a review of critical shortfalls as an agenda item at a future Authority meeting.**
Item 14	**Exploration of Risk Area – HTA Staff Induction**
	61. The Chair introduced this item and reminded the Committee that they had previously elected to explore the HTA's induction procedures. Members had been provided with relevant documents by Diane Galbraith which were taken as read.

62. Members noted that many of the issues raised for discussion were covered in the information provided. Members commented that finding the right balance of information provision at induction was challenging, but that a good suite of documents was under development. Members also positively noted the reference to HTA culture and SMT visibility during the induction process.

63. Members provided feedback on a number of areas including version control, consistency of language, performance management, the level of detail in Standard Operating Procedures and the inclusion of an introductory document.

64. Members raised the lack of training in interview skills for hiring managers as a risk. Diane Galbraith informed the Committee that she sat on the panel for the majority of interviews, however this was already recognised as a risk by the Executive and all managers would shortly be undertaking unconscious bias training. Members also asked that training included candidate selection.

65. Members asked for clarification on how the induction programme would be rolled out more widely. Diane Galbraith explained that although the first focus is Regulation Manager induction, this will be followed by more general induction across other roles.

66. Members queried the form for probationary assessment and whether it encouraged the provision of detailed evidence. Diane Galbraith provide assurance that this form would only be used for employees who pass their probation and continue in employment with the HTA. Poor performance during the probationary period would be managed through the performance management policy, with appropriate records kept.

67. Members asked for clarification on the competency assessment for inspectors. Members were given assurance that a Head of Regulation observes and signs off an inspector as competent to support an inspection, which then follows with a sign off as competent to lead an inspection by the relevant Head of sector.

68. Members emphasised that Cyber Security must form part of the induction process, as close to the inductee's start date as possible.

69. Members thanks Diane Galbraith for providing the information

	requested and for attending the meeting. **Action 12: Diane Galbraith to give further consideration to training for hiring managers** **Action 13: Diane Galbraith to liaise with David Thomson to ensure that Cyber Security training is incorporated consistently into induction processes for all new starters**
Item 15	**HTA Reserves Policy – (AUD 24/18)**
	70. Richard Sydee presented an update on the HTA's Reserves Policy HTA-POL-049 and the amendments made to the cash levels following the discussion at the 19 June 2018 ARAC meeting [ARAC Paper – (AUD 24/18)]. 71. The Committee highlighted that the high level of reserves was an area they have previously raised; Members discussed the revised policy in light of external factors including the UK's exit from the European Union. 72. The Committee approved the updated Policy in principle, however this is subject to a decision from DHSC on the business case to run a deficit for a period in order to invest in the HTA's transformation, and thus reduce the level of reserves.
Item 16	**Review of ARAC Handbook – (AUD 25/18)**
	73. Morounke Akingbola presented the HTA's Audit and Risk Assurance Committee Handbook for review by the Committee [ARAC Paper – (AUD 25/18)]. 74. Members emphasised the importance of receiving papers and minutes within reasonable timeframes to ensure effective functioning of the Committee. 75. Members agreed the updates to the Handbook, including the Terms of Reference, which will be approved by the Authority at their next meeting.
Item 17	**Reports on grievances, disputes, complaints, fraud and other**

	information (Oral)
	76. Allan Marriott Smith confirmed that there had not been any new grievances, disputes or incidents of fraud since the 19 June 2018 ARAC meeting. Members were advised that a settlement had been agreed with regard to a legal case brought against HTA.
Item 18	**Topics for future risk discussions (Discussion)**
	77. Members considered possible topics for future risk exploration sessions. The Committee elected to explore the risk and assurance associated with preparedness for the transformation programme as a collaborative exercise between the Executive and ARAC Members.
Item 18	**Topics for future ARAC training (Discussion)**
	78. The committee discussed possible topics for future training sessions. Members confirmed that the NAO would be invited to present on the issues and challenges experienced by other ARACs at the 12 February 2019 meeting. **Action 14: Chair to confirm arrangements with NAO for the presentation**
Item 19	**Any other business – Oral**
	79. The Chair invited those present at the meeting to identify any other business that they would like to discuss. 80. No other items of business were identified.

The meeting closed at 14.00

HTA Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	12 February 2019	**Paper reference**	AUD (28/18)
Agenda item	4	**Author**	
Protective Marking	OFFICIAL		

Matters Arising from 23 October 2018 and forward plan

Purpose of paper

1. The purpose of this plan is to enable members of the Audit and Risk Assurance Committee (ARAC) to monitor the matters arising from previous meetings and to consider progress against the recorded actions. The plan also enables members to identify agenda items, training requirements and to identify areas of concern to be explored in depth at future meetings.

Decision-making to date

2. To be reviewed and updated at each ARAC meeting.

Action required

3. The Members of ARAC are asked to:

   a) Review and where necessary revise the content and scheduling contained within forward looking sections of the plan.
   b) Note progress against the matters arising from previous meetings.

Background

4. Members are asked to note the matters arising from previous ARAC meetings, which are recorded within the Committee's Matters arising and forward plan. Any outstanding actions will be addressed within the agenda of the next ARAC meeting. Items not addressed within the agenda are summarised below.

Matters arising

From 2 November 2017

5. The HTA SMT to ensure that the findings arising from the project undertaken to address risks in the Human Application Sector are reflected within the HTA risk registers. This item remains open.

From 19 June 2018

6. Members recently received instructions to enable them to install the Blackberry 'Work' app on to their personal devices. Work was carried out at The Authority Strategy Away Day on the 25 September 2018. An update is to be provided.

From 23 October 2018

7. The Committee to receive an update on IT resourcing from the Head of Business Technology.

8. Head of HR to liaise with the Head of Business Technology to ensure Cyber Security training incorporated consistently into the induction process.

9. Internal Audit to conduct a follow-up review on Cyber Security. An update will be provided by Internal Audit at the meeting.

10. The Critical Incident Response Plan (CRIP) was circulated to Member for comment. An update on the amended plan to be given at the meeting

11. The Director of Regulatory Delivery to consider the feasibility of including some of the data from the safety KPI work into the Delivery Report. An update will be provided at the meeting.

HTA Audit and Risk Assurance Committee

Matters arising and forward plan

Tuesday 12 February 2019

HTA Audit and Risk Committee Matters arising

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
1	11 February 2016	8. Provide Gifts and Hospitality Register entries annually to ARAC	Head of Finance	February 2017	Completed - added to forward plan	Complete
2	11 February 2016	11. Include in the forward plan another observation and feedback from another ARAC Chair in 2017	Director of Resources	May 2016	Completed - added to forward plan	Complete
3	10 November 2016	20. Circulate the Business Continuity and Crisis Management response plan to ARAC	Director of Resources	November 2016	Completed. KW attached a copy to the meeting papers for the February 2017 meeting.	Complete
4	10 November 2016	21. ARAC members to receive an update on the risk of complaints and complaints handling at the HTA at the ARAC meeting in November 2017.	Chief Executive	November 2017	Completed. This item has been added to the forward plan	Complete
5	10 November 2016	22. RS to discuss the remainder of the 2016/17 internal audit plan with the Exec and advise ARAC of any amendments via email	Director of Resources	February 2017	RS Met with JN and draft annual plan reviewed by SMT. 2016//17 An agenda item for the ARAC Meeting on 18 May. Members were assured by JN that the 2016/17 Audit Plan was now complete. Findings from the Crisis Management Exercise and Quality Governance Advisory Review added to the Audit Tracker and discussed at the meeting. Enquiries Audit findings added to Tracker. JN agreed to adopt IA follow-up responsibility on all remaining actions within the tracker.	Complete
6	10 November 2016	23. Management should seek clarification from the relevant establishment and provide feedback to ARAC members on the reasons for the one remaining IA without a completed DBS check.	Director of Resources	February 2017	The IA with the outstanding DBS check did not pass the reaccreditation process because only one assessment had been undertaken and the requirement is for a minimum of two assessments to be undertaken. We have written to say that in addition, despite numerous attempts to contact the IA, no information was provided on the DBS check and therefore the IA has not been reaccredited for the 2017 / 18 business year. This item has been removed from the audit tracker.	Complete
7	10 November 2016	24. ARAC to reconsider the findings of the Living organ donation follow-up audit once the item in Action 23 has been further clarified.	Director of Resources	February 2017	Added to the agenda for the February 2017 meeting for ARAC to have a final look at the recommendation to remove this action/close this Audit. The remaining recommendations will be removed from the audit tracker, subject to the actions agreed at the ARAC meeting on 8 February 2017.	Complete
8	10 November 2016	25. Add an agenda item to the agenda for the February ARAC meeting for members to receive an update on the review of the Risk Management Policy and Strategy.	Head of Finance	February 2017	The latest iteration of this document was taken as read at the ARAC meeting on 8 February and incorporated within of the discussions within the joint ARAC/Staff afternoon training session. The action to update this document will be carried through as Action 8 arising form the 8 February ARAC meeting.	Complete
9	10 November 2016	26. Provide members of ARAC with an email update on the training of DIs and using inspection templates in the Post Mortem sector.	Director of Policy, Strategy and Communications	February 2017	AMS provided a verbal update at the next meeting on Post Mortem inspection templates. Kevin Wellard circulated a short email update bulletin to ARAC members before the February 2017 ARAC meeting. A deep dive on the HTA's interaction with DIs has been scheduled within the forward plan for November 2017.	Complete
10	10 November 2016	27. Add an agenda item to the agenda for the February ARAC meeting for members to consider the HTA's arrangements to address the recommendations emerging from the Caldicott review.	Director of Resources	February 2017	Completed.	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
11	8 February 2017	1. Confirm the status of items that the Committee agreed to remove from the tracker at the May meeting.	Director of Resources	May 2017	Items 6 & 9 of the Living Organ Donation Audit removed from tracker - Item 4 of the Living Organ Donation Audit to remain on the tracker Revised Guidance to transplant teams and Independent Assessors will be issued by the end of Q2. The delay was agreed as we need to have time to implement the two living donation policy changes, as those changes need to be reflected in the Guidance document. Members to be kept up to date via the ARAC Audit Tracker.	Complete
12	8 February 2017	2. Members to receive confirmation that Item 6 of the Living Organ Donation Audit has been incorporated into the HTA business plan at the May meeting.	Head of Finance	May 2017	Item 6 of the Living Organ Donation Audit have been removed from tracker.	Complete
13	8 February 2017	3. Morounke Akingbola to ensure that where due dates are not met or changed, the new due dates are included within the tracker and the old dates remain.	Head of Finance	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017 under item 7: progress against the Audit Tracker.	Complete
14	8 February 2017	4. Members to receive an update on developments related to the People and Workforce Audit at the May meeting.	Head of Internal Audit	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017 under item 7: progress against the Audit Tracker.	Complete
15	8 February 2017	5. Actions from the Enquiries Management Audit to be added to the audit tracker.	Director of Resources	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members were assured that the actions arising from the Enquiries Audit had been added to the Audit Tracker.	Complete
16	8 February 2017	6. Hazel Lofty to advise members whether teams have had occasion to procure specialised outside advice given the complexities of the sectors being regulated.	Head of Regulatory Development	May 2017	Members received an update from HL via an email from RS on 4 May 2017	Complete
17	8 February 2017	7. Managers to consider how the retrospective analysis of inspection findings could be cross-referenced with compliance updates for assurance purposes and report back to Members at the ARAC meeting in November 2017	Head of Regulatory Development	November 2017	This item has been added to the forward plan and is scheduled for November 2017.	Complete
18	8 February 2017	8. Morounke Akingbola to update the Risk Management Policy and Strategy based on comments from the risk workshop taking place after the meeting.	Head of Finance	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members approved this document subject to the completion of a number minor amendments. Members to receive an update under the matters arising item at the ARAC Meeting on 2 November. **Complete.**	Complete
19	8 February 2017	9. Morounke Akingbola to present the latest copy of the HTA Anti-fraud policy at the May meeting.	Head of Finance	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. This document was taken as read.	Complete
20	8 February 2017	10. Richard Sydee to present a draft update of the Gifts and Hospitality Policy to enable further discussion of these proposals at the May meeting.	Director of Resources	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members approved the revised Gifts and Hospitality policy subject the revision of the threshold value stipulated in paragraph 14, page three of the policy and circulation of the policy to all Authority members. Members to receive an update under the matters arising item at the ARAC Meeting on 2 November. **Complete.**	Complete
21	8 February 2017	11. Morounke Akingbola to update the Gifts and Hospitality register to include the attendance of the Chair and Dr Stuart Dollow at the health group non-executive directors' dinner hosted by PwC and to add where gifts or hospitality has been offered but refused.	Head of Finance	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members reviewed the latest format and content of the register.	Complete
22	8 February 2017	12. Richard Sydee to incorporate proposals to address the Caldicott Review within the annual review that is scheduled for consideration at the May meeting.	Director of Resources	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members received a report setting out the HTA's actions to address the 2016 Caldicott Review	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
23	8 February 2017	13. Allan Marriot-Smith to clarify the selection and reporting lines of a Caldicott Guardian at the May meeting.	Chief Executive	May 2017	This was an agenda item for the ARAC meeting on 18 May 2017. Members noted that AMS would remain CG pending the arrival of the new Head of Business Technology. Members will be advised under the matters arising item at the meeting on 2 November that David Thomson, The Head of Business Technology has been assigned to this role. **Complete.**	Complete
24	18 May 2017	1. Amend the Audit Tracker to reflect the ongoing nature of a number of the actions arising from the Enquiries Management Audit.	Head of Finance and Governance	November 2017	Members to receive an update under agenda item 6 at the ARAC Meeting on 2 November. **Complete.**	Complete
25	18 May 2017	2. Coordinate Department of Health feedback on the proposed scheduling of the Internal Audit cyber risk review during quarter three of the 2018/19 audit programme.	Roger Wallis, Department of Health	November 2017	Members to receive an update under agenda Item 7 at the ARAC Meeting on 2 November. **Complete.**	Complete
26	18 May 2017	3. Update risk two of the Strategic Risk Register: *Failure to manage an incident* – in order to reflect the findings and recommendations arising from the recent Crisis Management Exercise.	Director of Resources	November 2017	This item is now complete. Members are invited to review the strategic risk register under agenda Item 8 at the ARAC Meeting on 2 November. **Complete.**	Complete
27	18 May 2017	4. Update the Risk Management Policy and Strategy based on the comments received from ARAC members.	Head of Finance and Governance	November 2017	Members of ARAC are advised that the HTA Risk Management Policy and Strategy and has been updated to reflect the comments received from the committee at its meeting on 18 May. Members of ARAC will be given assurance of this under the matters arising item at the ARAC meeting on 2 November. **Complete.**	Complete
28	18 May 2017	5. Consider how the Department of Health would support the HTA and other health-based regulators in the absence of the EU based fora lost as a result of 'Brexit'.	Roger Wallis, Department of Health	November 2017	Members to receive an update under the matters arising item at the ARAC Meeting on 2 November. Members received an oral briefing on this item from the DH Brexit specialist at the Meeting on 2 November 2017. **Superseded by action 1 from the 2 November 2017.**	Complete
29	18 May 2017	6. Investigate the availability of any National Institute of Health Research programmes that might enable the HTA to gain access to scientific journals.	Prof. Andrew Hall	November 2017	Members to received an update under the matters arising item at the ARAC Meeting on 2 November. Following the discussions with the NIHR Innovation Observatory (IO), the IO is not well placed to assist the HTA with journal access, although its development plans may mean that it could help the HTA expand its future horizon scanning capabilities. The HTA will continue to monitor the development of the IO and set up further meetings as appropriate. **Complete**	Superseded
30	18 May 2017	7. Circulate a copy of the revised HTA Gifts and Hospitality Policy to all HTA Authority Members.	Head of Finance	November 2017	Members to receive an update under the matters arising item at the ARAC Meeting on 2 November. **Complete.**	Complete
31	18 May 2017	8. Advise the members of ARAC on the risks of people logging into HTA software from older / out of date software.	Director of Resources	November 2017	Members to receive an update under the matters arising item at the ARAC Meeting on 2 November. **Complete.**	Complete
32	18 May 2017	9. Provide Richard Sydee with an outline brief - to inform the preparation of an explanatory paper on the training of designated Individuals, by 30 June 2017.	ARAC Chair	November 2017	Brief provided. Members were due to explore this issue at the ARAC meeting on 2 November 2017. This item was postponed but has been captured in the forward plan to occur at a date to be confirmed. **Complete.**	Complete
33	18 May 2017	10. Invite the Chair of another ARAC Committee to attend the ARAC meeting on 2 November 2017 to provide Members with feedback and insights to inform their ongoing development.	Director of Resources	February 2017	Members are advised that an observer was invited but unable to attend the meeting. This event has been postponed until the 23 October 2018 ARAC Meeting.	Complete
34	18 May 2017	11. Arrange a budget update teleconference between Allan Marriot-Smith, The Chair and Sharmila Nebhrajani (Chair of the HTA)	Director of Resources	November 2017	Members to receive an in year Budget Review/update on approach 2018/19 Fees Modelling under agenda 10 item at the ARAC Meeting on 2 November. **Complete.**	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
35	18 May 2017	12. Investigate the implications of revoking licences at establishments due to unpaid licence fees.	Director of Regulation	November 2017	Members to receive an update on the prevention of and implications arising from bad debt provision under agenda item 13 at the ARAC Meeting on 2 November. **Superseded** by action 9 from the 2 November 2017.	Complete
36	18 May 2017	13. Coordinate Department of Health advice on the collection of debts from NHS Trusts and any implications concerning the HTA's bad debt provision.	Roger Wallis, Department of Health	November 2017	Members to receive an update on the prevention of and implications arising from bad debt provision under agenda item 13 at the ARAC Meeting on 2 November. Advice and guidance received from the DH. **Superseded by action 9 from the 2 November 2017.**	Complete
37	18 May 2017	14. Provide the committee with a coordinated update on the prevention of and implications arising from bad debt provision.	Director of Resources	November 2017	Members to receive an update on the prevention of and implications arising from bad debt provision under agenda item 13 at the ARAC Meeting on 2 November. **Superseded by action 9 from the 2 November 2017.**	Complete
38	2 November 2017	Action 1: Amy Thomas to draft a briefing paper to inform the negotiation process for the UK's exit from the EU.	Head of Regulatory Development	February 2018	Scheduled as an agenda item for the ARAC meeting on 2 February 2018. **Complete. Members received a paper on this item at the 2 February 2018 ARAC meeting. Agreed at Chair/SMT commissioning meeting that this will be a standing item in the risk update until during the transit period.**	Complete
39	2 November 2017	Action 2: Morounke Akingbola to remove items 1.b) and 2a) arising from the Critical Incident Exercise from the Audit Tracker.	Head of Finance and Governance	February 2018	Members to receive an update under the Audit Tracker update agenda item at the ARAC Meeting on 1 February 2018. **Complete**	Complete
40	2 November 2017	Action 3: Hazel Lofty to advise the Members of ARAC on the viability of addressing item 11 arising from the Quality Governance audit within the CRM upgrade project.	Director of Policy, Strategy and Communications	February 2018	Members received an update on this item under the matters arising item at the ARAC Meeting on 1 February 2018. This action is to be incorporated into the review of the revised licence application process. Licence applications to then be reviewed periodically by the Director and Heads of regulation at their governance meeting. **Complete.**	Complete
41	2 November 2017	Action 4: The SMT to undertake a comprehensive review of the ongoing viability and prioritisation of the items currently listed within the Audit Tracker.	Director of Resources	February 2018	Members to receive an update under the Audit Tracker update agenda item at the ARAC Meeting on 1 February 2018. the Tracker was reviewed by SMT. The revised Audit tracker was signed off by the ARAC committee at its meeting on 1 February 2018. **Superseded** by Action 1 arising from 1 February 2018 **(ledger number 52).**	Superseded
42	2 November 2017	Action 5: Kevin Wellard to schedule regular ARAC joint assessment of the headline strategic and operational risks within the committee's matters arising and forward plan.	Director of Policy, Strategy and Communications	February 2018	Members to receive an update under the matters arising item at the ARAC Meeting on 1 February 2018. The Committee asked Kevin Wellard to schedule regular ARAC joint assessment of the headline strategic and operational risks within the committee's matters arising and forward plan. This item has been added to the forward plan the first annual review of the ORR is proposed as an **agenda item** for the 19 June 2018 ARAC meeting.	Complete
43	2 November 2017	Action 6: The HTA SMT undertake a review of the Strategic Risk Register to clarify any discrepancies before presenting it to the Authority on the 9 November 2017.	Director of Resources	November 2017	The register was amended and presented to the Authority at its meeting on 9 November 2017. **Complete.**	Complete
44	2 November 2017	Action 7: The HTA SMT to ensure that the findings arising from the project undertaken to address Risks in the Human Application sector are reflected within the HTA risk registers.	Director of Regulation	February 2018	Members to receive an update under the matters arising and risk update agenda items at the ARAC Meeting on 1 February 2018. This item to remain open pending further discussion within the HTAMG on the most appropriate method of recording these risks. **Ongoing**	Live
45	2 November 2017	Action 8: The ARAC committee to receive an update on the HTAs preparations to upgrade the current CRM system.	Head of Business Technology	February 2018	Members received an update on this item at the 1 February 2018 ARAC meeting. **Complete**	Complete
46	2 November 2017	Action 9: The ARAC committee to receive proposals for an oversight strategy on Third Party Agreements within the Human Application Sector.	Director of Policy, Strategy and Communications	June 2018	Added in January 2017 to reflect comments on the minutes received from Stuart Dollow. This item as been added to the **agenda** for the 19 June ARAC meeting.	TBC at ARAC meeting on 12 Feb 2019

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
47	2 November 2017	Action 10: The Members of ARAC to receive an update on HTA debt recovery at the ARAC Meeting on 1 February 2018.	Director of Resources	February 2018	Scheduled as an agenda item for the ARAC meeting on 1 February 2018. The Members of ARAC received a paper on this item at the 1 February 2018 ARAC meeting. **Complete.**	Complete
48	2 November 2017	Action 11: Morounke Akingbola to amend the latest iteration of the HTA ARAC Handbook as directed by the ARAC committee on 2 November 2017.	Director of Resources	February 2018	**Complete.** Members received confirmation va the matters arising item of the 1 February 2018 ARAC meeting.	Complete
49	2 November 2017	Action 12: At the ARAC meeting in February 2018, the Members of ARAC will consider the need for an additional Meeting between May and November 2018 to discuss any implications and risks emerging from the UK leaving the EU.	Members of ARAC	February 2018	Scheduled as an agenda item for the ARAC meeting on 1 February 2018. This item has been superseded by the revised scheduling of ARAC meeting for 2018 to occur on 19 June and 23 October. **Superseded.**	Superseded
50	2 November 2017	Action 13: It was agreed that the Members of ARAC would receive interim guidance on the use of personal information when corresponding with the LDAT and LDC.	Director of Regulation	February 2018	**Ongoing.** This item is due to be addressed via the HTA's preparations to adhere to the GDPR. In the meantime, Members recently received instructions to enable them to install the Blackberry 'Work' app on to their personal devices. This will enable Members to access their HTA accounts. Members will receive an update on this action under the **matters arising** item of the 18 June 2018 ARAC meeting.	Complete
51	2 November 2017	Action 14: Richard Sydee to present the findings of the review of the HTA/HFEA shared Services Directorate to the Authority and ARAC meetings in February 2018.	Director of Resources	February 2018	Scheduled as an agenda item for the ARAC meeting on 2 February 2018. **Complete.** Members received a paper on this item at the 2 February 2018 ARAC meeting.	Complete
52	1 February 2018	Action 1: Kevin Wellard to schedule critical incident exercises within the ARAC forward plan and Corporate Business Plan Tracker to occur at approximately 12-18 month intervals.	Director of Policy, Strategy and Communications	June 2018	The members of ARAC will receive an update on this item under the **matters arising** item and **item 12** of the agenda for the 19 June 2018 ARAC meeting.	To be added to 2019/20 business plan
53	1 February 2018	Action 2: Richard Sydee to track the HTA's critical incident readiness within the HTA Strategic Risk Register.	Director of Resources	June 2018	The members of ARAC will receive an update on this item under the **matters arising** item and **item 12** of the agenda for the 19 June 2018 ARAC meeting.	Complete
54	1 February 2018	Action 3: Morounke Akingbola to add a high/medium/low priority rating to the actions recorded within the Audit Tracker.	Director of Resources	June 2018	Audit tracker to be reviewed as a standard **agenda item** at the 19 June ARAC meeting	Complete
55	1 February 2018	Action 4: Morounke Akingbola to amend the commentary within the Audit tracker to reflect the status of the actions arising within the Internal Audit Cyber Security Report.	Director of Resources	June 2018	Audit tracker to be reviewed as a standard **agenda item** at the 19 June ARAC meeting	Complete
56	1 February 2018	Action 5: Richard Sydee agreed to consider the feasibility of introducing enhanced security vetting for new employees with access to the HTA's most sensitive data.	Director of Resources	June 2018	The Director of Resources will provide members with an update on this issue under the matters arising or **item 13 of the agenda** at the 19 June 2018 ARAC meeting.	Complete
57	1 February 2018	Action 6: George Smiles to circulate copies of the NAO guidance to ARAC committees on cyber security.	NAO	June 2018	Links provided by GS. Circulated by KW as links and attachments 24/4/18. **Complete.**	Complete
58	1 February 2018	Action 7: The Members of the ARAC to receive copies of the minutes arising from the GDPR project meetings.	Director of Resources	June 2018	The Committee will receive an update on this action under **item 13 of the agenda** for the 19 June 2018 ARAC meeting.	Complete
59	1 February 2018	Action 8: Richard Sydee to explore options to provide ongoing assurance to the ARAC prior to the implementation of the GDPR.	Director of Resources	June 2018	The Committee will receive an update on this action under **item 13 of the agenda** for the 19 June 2018 ARAC meeting.	Complete
60	1 February 2018	Action 9: Jeremy Nolan to provide the ARAC with a draft HTA Internal Audit Plan for 2018/19 by the end of February 2018.	Head of Internal Audit	June 2018	This action is an item on the **agenda** for the 19 June 2018 ARAC meeting.	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
61	1 February 2018	Action 10: Morounke Akingbola to revise paragraph's 12 and 13 of the HTA Risk Management Strategy and Policy.	Director of Resources	June 2018	**Complete.**	Complete
62	1 February 2018	Action 11: members of the Committee and other nominated participants to complete the ARAC baseline self-assessment questionnaire and return it to the Chair of the ARAC.	Members of ARAC	June 2018	**Complete.** The annual self assessment report is scheduled for presentation as an item on the **agenda** for the19 June 2018 ARAC meeting.	Complete
63	1 February 2018	Action 12: Kevin Wellard to add an additional question to the Committee's baseline Annual Self-assessment questionnaire to consider the ongoing value for money of member expenditure.	Director of Policy, Strategy and Communications	June 2018	**Complete.** The Committees baseline annual - self-assessment has been updated and a copy of the revised questionnaire has been added to the February 2019 ARAC folder in Impact. Members will receive an update on this action under the matters arising item of the19 June 2018 ARAC meeting	Complete
64	1 February 2018	Action 13: Richard Sydee to provide the members of ARAC with a background paper on HTA historical cash flows.	Director of Resources	June 2018	This action is an item on the **agenda** for the 19 June 2018 ARAC meeting.	Complete
65	1 February 2018	Action 14: Members to consider the approval of the draft HTA Reserves Policy at the ARAC Meeting on 19 June 2018.	Director of Resources	June 2018	This action is an item on the **agenda** for the 19 June 2018 ARAC meeting.	Complete
66	19 June 2018	Action 1: Dr. Stuart Dollow agreed to convene contact between HTA executive and the National Institute for Health and Care Excellence to explore additional options to support the HTA's continuous corporate development.	Dr. Stuart Dollow	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
67	19 June 2018	Action 2: The ARAC committee to receive confirmation of Authority Member access and usage of the recently supplied Blackberry 'Work' app, at the 23 October 2018 ARAC meeting.	Director of Resources	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Ongoing - update to be provided at 12 Feb 19 meeting
68	19 June 2018	Action 3: Richard Sydee to invite the HTA Data Protection Officer, Dan Howard, to attend the 23 October 2018 ARAC meeting.	Director of Resources	October 2018	Repeated as an action at arising from 23 October 2018 ARAC Meeting	Superseded
69	19 June 2018	Action 4: The ARAC to receive a performance update on the closure of CAPA's (KPI 4) at its meeting on 23 October 2018.	Director of Resources	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	TBC at ARAC meeting on 23 October 2018
70	19 June 2018	Action 5: Richard Sydee to provide members with an update on the HTA's incorporation of a notification of access proforma, to inform staff IT access permissions at the 19 July Authority Meeting.	Director of Resources	July 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
71	19 June 2018	Action 6: Nicola Blackwood to discuss the feasibility of updating existing Human Tissue legislation with the Minister for Mental Health and Equalities on 11 July 2018.	HTA Chair	July 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
72	19 June 2018	Action 7: Kevin Wellard to schedule a follow-up review of the revised Operational Risk Register by the ARAC at its meeting on 23 October 2018.	Direcetor of Regulatory Development	October 2018	This item has been added to the added to the ARAC forward plan and will be addressed under the standing **Risk update** item at the 23 October 2018 ARAC meeting.	Complete
73	19 June 2018	Action 8: Members to receive a follow-up report on the development of an oversight strategy for Third Party Agreements within the Human Application Sector, at the ARAC meeting in February 2019.	Head of Regulatory Development	February 2018	This item has been added to the Added to the ARAC forward plan. Update scheduled for February 2019 meeting	Complete
74	19 June 2018	Action 9: The executive to present an updated version of the Critical Incident and Response Plan at the 23 October 2018 ARAC meeting.	Director of Resources	October 2018	This item has been added to the Added to the ARAC forward plan and will be added to the **agenda** for the 23 October 2018 ARAC meeting.	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
75	19 June 2018	Action 10: ARAC to review a copy of the HTA's Assurance map at its meeting in February 2019.	Director of Regulatory Development	February 2019	This item has been added to the Added to the ARAC forward plan.	TBC at ARAC meeting on 23 October 2018
76	19 June 2018	Action 11: ARAC members to receive a copy of the HTA GDPR compliance tracking spreadsheet by the end of July 2018.				Complete
77	19 June 2018	Action 12: Members to explore the risks and assurance arising from the HTA staff induction process at its meeting on 23 October 2018	Chief Executive	October 2018	This item has been added to the added to the ARAC forward plan and will be added to the **agenda** for the 23 October 2018 ARAC meeting.	Complete
78	19 June 2018	Action 13: David Thomson to provide the ARAC with confirmation of the tracking arrangements supporting the HTA's eLearning arrangements.	Head of Business Technology	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
79	19 June 2018	Action 14: Cyber Security to be recorded within the ARAC Forward plan as a standing agenda item for future ARAC meetings	Head of Regulatory Development	October 2018	This item has been added to the Added to the ARAC forward plan.	Complete
80	19 June 2018	Action 15: Richard Sydee to develop a business case to the DHSC, setting out the HTA's proposal to amend its reserves policy.	Director of Resources	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
81	19 June 2018	Action 16: Kevin Wellard to circulate the latest iteration of the ARAC baseline self-assessment questionnaire to Committee members.	Head of Regulatory Development	October 2018	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 23 October 2018 ARAC meeting.	Complete
82	23 October 2018	Action 1: RS to invite the HTA Data Protection Officer to attend a future ARAC meeting	Director of Resources			
83	23 October 2018	Action 2: Completed items from the Corporate Governance and Financial Control audits to be removed from the tracker.	Head of Finance and Governance			
85	23 October 2018	Action 3: The Committee to receive an update on IT resourcing at the 12 February 2019 ARAC meeting.	Director of Resources	February 2019	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 12 February 2019 ARAC meeting.	Live
87	23 October 2018	Action 4: Internal Audit to conduct follow up review on Cyber Security and provide an update at the 12 February 2019 ARAC meeting	Head of Internal Audit	February 2019	The members of ARAC will receive an update on this item under the **internal audit update** item of the agenda for the 12 February 2019 ARAC meeting.	Live
88	23 October 2018	Action 5: Jeremy Nolan to facilitate further discussion/training for ARAC Members on risk updates at a future ARAC meeting	Head of Internal Audit			
89	23 October 2018	Action 6: Richard Sydee to provide ARAC Members with an update on GDPR implementation progress ahead of the February ARAC meeting.	Director of Resources	February 2019	RS shared by email with ARAC Members on 21 December 2018.	Complete
90	23 October 2018	Action 7: Training on GDPR obligations to be added to the Authority forward plan to coincide with Cyber Security training	Director of Regulatory Development		Added to the Authority training plan	Complete
91	23 October 2018	Action 8: Electronic version of the updated CIRP to be emailed to Members	Director of Resources	February 2019	RS shared by email with ARAC Members on 21 December 2018.	Complete
92	23 October 2018	Action 9: Members to provide comments on the updated CIRP to Richard Sydee via email	Director of Resources	February 2019	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 12 February 2019 ARAC meeting.	Live
93	23 October 2018	Action 10: ANH to consider the feasibility of including some of the data from the safety KPI work into the Delivery Report	Director of Regulatory Delivery	February 2019	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 12 February 2019 ARAC meeting.	Live
94	23 October 2018	Action 11: The Executive to consider adding a review of critical shortfalls as an agenda item at a future Authority meeting.	Director of Regulatory Delivery	February 2019	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 12 February 2019 ARAC meeting.	Live
95	23 October 2018	Action 12: Diane Galbraith to give further consideration to training for hiring managers	Head of HR	February 2019	Mandatory trainng has been arranged for all hiring managers. This will take place on 4 March 2019	Complete

Ledger number	Meeting	Action	Responsibility	Due date	Progress to date	Status
96	23 October 2018	Action 13: Diane Galbraith to liaise with David Thomson to ensure that Cyber Security training is incorporated consistently into induction processes for all new starters	Head of HR	February 2019	The members of ARAC will receive an update on this item under the **matters arising** item of the agenda for the 12 February 2019 ARAC meeting.	Live
97	23 October 2018	Action 14: Chair to confirm arrangements with NAO for the presentation on challenges faced by other ARAC's	ARAC Chair	February 2019	This training course has been postponed and has been replaced with a training session on Improving Audit Committee Effectiveness	Superseded

Risk exploration topics

Topic	Meeting	Progress
Risks posed by sectors and the HTA's approach to protect public confidence • The HTA Inspection Rationale	February 2017	On the agenda for the February 2017 meeting. **Complete.**
Risks posed by sectors and the HTA's approach to protect public confidence Breadth of activity, regulatory approach and risk assessments for various aspects of the Human Application Sector – Follow-up from Authority seminar in February 2017.	May 2017	This item has been scheduled to occur as a follow up to the authority member seminar scheduled for the morning of the February Authority Meeting. **Complete.**
HTA interaction with DIs/DI Training and Recruitment	November 2017	Due to competing work priorities within the Regulation Directorate, The Chair of ARAC has agreed replace this topic with an item looking at the recommendations arising the from the Risks in the Human Application Sector project. We will seek another date for the DI work deep dive, but the meeting after next is likely to look at recruitment and retention risks.
Risks in the Human Application Sector project.	November 2017	Complete.
Management and succession arrangements to assure the continuity of licensing and regulation activity	February 2018	Complete.
Risks associated with Cyber Security	June 2018	Complete. To be added as Standing Item.
Risks associated with the HTA's Licensed Establishment Relationship programme	TBC	As agreed at the 1 February 2018 ARAC Meeting. At 19 June 12018 ARAC Meeting, the Committee agreed to postpone its investigation of the HTA's Licensed Establishment Relationship Programme, which was scheduled for 23 October 2018 ARAC meeting. The Committee elected instead, to explore the risks and assurance associated with the HTA's staff induction process.
The risks and assurance associated with the HTA's staff induction process.	October 2018	At 19 June 12018 ARAC Meeting, the Committee elected to explore the risks and assurance associated with the HTA's staff induction process.
HTA continuous business planning arrangements for the triaging of business planning activity	TBC	Originally scheduled for 19 June 2018 but postponed by the ARAC committee at its meeting on 1 February 2018. New date TBC.
Media handling,	TBC	
Risks posed by sectors and the HTA's approach to protect public confidence.	TBC	
Post Mortem sector (due at Authority Meeting 04 May 2017)	TBC	

Future training

Topic	Meeting	Provider	Progress
Joint ARAC Member/Management Team training seminar – undertaking risk assurance mapping and interdependency across the wider health group	February 2017	Internal Auditor/Director of Resources	To focus on wider suggested best practice in accordance with the Risk Management Policy and Strategy and consideration of wider interdependence across the health group. **Complete.**
Value for money auditing and the optimal deployment of resources		NAO	NAO have been invited to host a training session on 18 May 2017. **Complete.**
A NAO perspective on the risks emerging within the health sector	February 2018	NAO Catherine Hepburn	**Complete**.
Observation and feedback from another ARAC Chair	June 2018	Anne Beasley, formerly Director General of Finance and Corporate Services at the UK Ministry of Justice	Rescheduled to occur after the ARAC meeting in June 2018 but postponed until 23 October due to the availability of the observing Chair.
Observation and feedback from another ARAC Chair	October 2018	Anne Beasley, formerly Director General of Finance and Corporate Services at the UK Ministry of Justice	Rescheduled to occur after the ARAC meeting in June 2018 but postponed until 23 October due to the availability of the observing Chair.
NAO presentation the issues and challenges experienced by other ARACs.	February 2019	George Smiles,(NAO)	At the ARAC meeting on 01 February 2018, Members invited George Smiles to provide them with a presentation at the October ARAC meeting on the issues and challenges experienced by other ARACs. **Postponed**
Training and/or discussion on risk updates - ensuring Members gain assurance on how risks are recorded and managed.	TBC	Jeremy Nolan, (GIAA)	At the ARAC meeting on 23 October, Members invited Jeremy Nolan to facilitate discussion on risk management and how Members can assure themselves that risks are being managed and recorded correctly.
	June 2019	TBC	
	October 2019	TBC	
	February 2020	TBC	

Forward plan **Forward Plan**

Standing items	Assurance reports from Internal Audit Audit recommendations tracker report Risk update includes strategic risk register review and **update on UK exit from the EU.** Polices/procedures updates Cyber security (as requested by the ARAC on 19 June 2018)	
Meeting		
February 2018	Review and approval of the Internal Audit proposed Audit plan for the financial year 2019/20 Review of the Audit & Risk Assurance Committee's performance including Members' skills and training Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting) Review gifts and hospitality register Update on the review of the risk management policy and strategy	
June 2018	Approval of the Annual Report and Accounts Review of the External Auditors ISA 260 report (management letter) Consider key messages for the Audit & Risk Assurance Committee's report on its activity and performance (to the Authority) Review and approval of the Internal Audit proposed Audit plan for the financial year Internal Audit Annual statement. (Draft Note: RS to discuss the approach to this with PF, Information Risk management - SIRO report Annual review of the Operational Risk Register	To consider a draft update of the HTA Gifts and Hospitality Policy Incorporation of draft proposals to address the Caldicott Review within the annual review
October 2018	Review of HTA Reserves Policy Review of ARAC Handbook Review of Gifts & Hospitality Register	Update on complaints and complaints handling at the HTA Management proposals for the cross-referencing of inspection findings with compliance updates Review of ARAC Handbook At the 19 June 2018 ARAC meeting, The Committee agreed to invite the HTA's Data protection Officer Dan Howard to attend the 23 October 2018 ARAC meeting. At the 19 June 2018 ARAC meeting, The Committee requested a follow-up review of the revised Operational Risk Register at the its meeting on 23 October 2018. At the 19 June 2018 ARAC meeting, The Committee requested that Executive to present an updated version of the Critical Incident and Response Plan at the 23 October 2018 ARAC
February 2019	Review and approval of the Internal Audit proposed Audit plan for the financial year 2020/21 Review of the Audit & Risk Assurance Committee's performance including Members' skills and training. Hold confidential joint meeting with both sets of Auditors (agenda item at start or end of meeting) Review gifts and hospitality register Update on the review of the risk management policy and strategy Annual review of the Operational Risk Register	At the 19 June 2018 ARAC meeting, The Committee requested a follow-up report on the development of an oversight strategy for Third Party Agreements within the Human Application Sector, at the ARAC meeting in February 2019. At the 19 June 2018 ARAC meeting, The Committee asked to review a copy of the HTAs Assurance map at its meeting in February 2019

Internal Audit Update- Confidential

HTA
Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	12 February 2019	**Paper reference**	(AUD 30/18)
Agenda item	8	**Author**	Morounke Akingbola Head of Finance and Governance
Protective Marking	OFFICIAL / CONFIDENTIAL		

Audit Tracker Update

Purpose of paper

1. The purpose of this paper is to update the Audit and Risk Assurance Committee on the progress made in response to external and internal audit recommendations.

Decision-making to date

2. As detailed in the progress sections of this paper. There has been one advisory audit since the last committee meeting in October 2018.

Action required

3. Members of ARAC are required to:

   a) Consider the HTA's overall progress on the delivery of actions arising from internal and external audit recommendations.
   b) Approve the removal of proposed recommendations as listed below and highlighted in blue in the Tracker

Update

4. All recommendations made in the Corporate Governance and Financial controls audit reports have been completed and evidence provided to Internal Audit. We request that these be removed from the tracker.

5. Two of the recommendations from the Cyber Security audit are complete subject to the Committee's agreement. Two remain outstanding.

Summary of all recommendations

Recommendation Source	Total	Completed as planned	Completed later than expected	In progress as planned/on going	In progress with some delay	Removed as directed by Committee	Not started or N/a
IA – Corporate Governance – Risk Mgt	**4**	**2**	2	0	0	**0**	**0**
IA - Cyber security	**6**	**2**	2	0	2	**0**	**0**
IA - Financial Controls	**1**	**0**	1	0	0	**0**	**0**
COUNT	**11**	**4**	**5**	**0**	2	**0**	**0**

IA – Internal Audit – PwC/DH
EA – External Audit - NAO

HIGH	**1**				1		
MEDIUM	**5**	**3**			2		
LOW	**5**	**3**	**1**		1		

Detail - outstanding recommendations

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
2017/18			
Corporate Governance	Operational Risk Register - A significant amount of information concerning the management of risk missing from the operational risk register		
1. HTA should ensure, as part of the formal arrangements for the review and discussion of its risk registers within HTAMG that all Directorate risk registers are complete	Director of Resources (DoR) to review each operational risks with individual Risk Holders to ensure completeness of templates. HTAMG to review operational risk register in full at a risk focussed meeting ***Target date – December 2017***	**November 2017** – Review to be undertaken prior to next HTAMG meeting **May 2018** - Completed	Richard Sydee **Completed** **Remove**
Corporate Governance	Inconsistencies in scoring and categorisation of control - noted in some instances that HTA was not following its assessment methodology and this could lead to risks not being escalated as they should be for the attention of senior management. Furthermore, we also found several examples of controls and assurance sources being misclassified within risk registers with the result that a misleading picture could emerge of the mitigation and its success (or otherwise in managing risk)		
2. HTA should review risk registers to ensure that risk scores are accurate and in accordance with corporate policies and objectives.	Following the monthly SMT risk discussion the strategic RR will be amended by DoR, with scores checked for accuracy/consistency by Head of Finance (HoF) before RR is finalised. ***Target date – October 2017***	**November 2017** – Both register scorings were reviewed by DoR/HoF in line with risk policy	Richard Sydee **Completed** **Remove**
3. HTA management upon the review of risk registers should ensure that mitigation and assurance is correctly categorised. In addition, it should ensure that the nature and scope of assurance is described.	Director of Resources will review mitigation and assurance within the strategic and operational risk registers with Risk holders – changes to be highlighted at November SMT	**November 2017** – On-going. Activity planned for mid/late November **May 2018** - Completed	Richard Sydee **Completed** **Remove**

	Risk discussion for strategic RR; December HTAMG for operational RR ***Target date – December 2017***		
Corporate Governance	Contingency Actions - HTA does not set-out its contingencies in its risk registers. Although this point is not material at this moment in time (given that risk is uniformly reported as being managed within acceptable levels) it does mean that contingencies are not subject to review via the risk management process. Therefore management will not have assurance that they will operate as intended should they be required		
4. HTA should develop contingencies should for its risks so their effectiveness can be considered in the risk management process.	HoF will discuss possible contingencies with individual Risk Holders and propose format change for RRs to incorporate contingencies for 2018/19. **Target date – March 2018**	**November 2017** – HoF to have discussions during budget planning (Dec-Jan) **February 2018 –** HTAMG met in January to discuss contingencies. Whilst some of our risks lend themselves readily to a plan B, not all do. Summary document appended to Operational risk register being produced. **May 2018** - Completed	Morounke Akingbola **Completed** **Remove?**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Cyber security	Security – lack of forensic readiness That in the event of an external or internal attack or information security incident on HTA's IT infrastructure, there is an inability to effectively secure appropriate digital evidence to ensure there is a robust audit trail, and for use in support of any resulting legal or disciplinary action.		
We recommend that HTA develops and applies a system of forensic readiness which ensures they can provide an appropriate level of capability to collect, preserve, protect and analyse digital evidence of any unwanted or unforeseen event impacting its IT systems. We further recommend this should be in accordance with the NHS Digital 'Forensic Readiness Good Practice Guide'.	David Thomson to create a forensic readiness specification that can be agreed with a number of providers *Target date - January 2018* ***New target date – Difficult to say as work is complex.***	**May 2018** – Forensic readiness policy has been written into the HTA's contract with BCC. The next stage is to compose a plan to implement the policy. **October 2018** - Contract has been re-tendered. On award, work will begin on forensic readiness spec. **February 2019** Contract variation with BCC is to be finalised by the end of February.	David Thomson
Cyber security	Policy – notification of access permission changes That staffing changes such as leavers and role changes are not made known by Human Resources to IT services to allow the timely amendment or termination of access permissions on the effective date of the change. Where an appointment is made to a post which has access to HTA's most sensitive information there is no form of enhanced vetting		
We recommend that HTA Human Resources develop and implement a formal system which notifies IT services of staff leaving or moving roles so that any required amendments to access permissions can be made in a timely manner.	David Thomson and Diane Galbraith to agree a pro forma for all starters, leavers and job role changes to ensure that accounts are created, suspended or amended as their employment with HTA changes or ends ~~*Target date – January 2018*~~	**May 2018** – This has been included as part of the GDPR work scheduled over the next six months **October 2018** -Documentation has been drafted and process agreed. Documentation awaiting sign-off	Diane Galbraith

	New target date -	**February 19 – Implementation and communication plan to be agreed in Februarywith target launch of new process in March.**	

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
Cyber security	Contracts – requirement for serer room protection There is a risk that sensitive HTA data is not disposed of in a secure manner, causing the data to obtained or viewed by other parties, potentially breaching legislation or causing serious reputational damage to HTA and any individuals or organisations to which the data pertains		
HTA should verify the adequacy of the environmental controls provided for its server room are sufficient to bring risks to the operation of their servers within HTA's risk appetite for such. This should then be addressed with HTA's landlord to obtain written agreement to the ongoing provision of the required environmental controls	David Thomson will discuss the current environmental controls with the landlord and ensure they are in line with in house requirements. ~~*Target date – March 2018*~~ ***New target date – October 2018***	**May 2018** – Conversation had with BEIS regarding the environmental controls. Awaiting assurance from BEIS. **October 2018 -**This has been discussed with the landlord and we have accepted that the current environmental controls and fire suppressant capability is adequate for HTA's appetite for this risk. The ongoing provision is implicit within the HTA's moto for 151 Buckingham Palace Road	David Thomson **Complete** **Remove**

Cyber security	Contracts – requirement for certification of information destruction There is a risk that sensitive HTA data is not disposed of in a secure manner, causing the data to obtained or viewed by other parties, potentially breaching legislation or causing serious reputational damage to HTA and any individuals or organisations to which the data pertains		
We recommend that HTA agrees with its IT service supplier that, when the latter disposes of data, certification is provided that all data has been overwritten to approved standards before disposal of any equipment	David Thomson will discuss a revised process for the disposal of all storage media, ensuring that all such destructions are confirmed and certified by BCC. *Target date – January 2018* ***New target date – November 2018***	**May 2018** – This has been done however DT needs to follow-up with BCC regarding the certificates of destruction due to the change in IT support personnel. **October 2018 -** This has been agreed and certificates will be provided for the destruction of all hard drives as part of the forthcoming disposal of obsolete laptops. **February 2019 –** Laptops not in condition to resell have been disposed of and certificate of destruction of hard drives has been received and shared with Internal Audit.	David Thomson **Complete** **Remove**

RECOMMENDATION	AGREED ACTIONS	PROGRESS	OWNER / COMPLETION
2017/18			
Financial Controls	All policies and procedural documentation should be formally reviewed on regular basis (at least annually) and approved with a new review date being set and recorded within the documents version control.		
1. HTA should ensure, as part of the formal arrangements for the review and discussion of its risk registers within MTAMG that all Directorate risk registers are complete	Accepted: Generally the policies are reviewed regularly, however those highlighted will be reviewed by 31 March ~~***Target date – 31 March 2018***~~ ***New target date – September 2018***	**February 2018** – Review has commenced with Procurement and Budgetary Control policies. **May 2018 –** All policies have been reviewed and further review and amendment is required on the expenses policy following a benchmarking exercise that is being undertaken. **October 2018** Policy review completed in September. A revised expense policy was reviewed by SMT and accepted with some changes **February 2019** Expense policy shared with staff and to be released in April 2019. Copies shared with GIAA in January.	Morounke Akingbola In progress **Complete** **Complete**

HTA
Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	12 February 2019	**Paper reference**	AUD (31/18)
Agenda item	9	**Author**	Richard Sydee Director of Resources
	OFFICIAL		

Risk Update

Purpose of paper

1. To provide ARAC with an update on HTA's strategic risks and proposed mitigations at February 2019.

Decision-making to date

2. None

Action required

3. ARAC Members are required to comment on the strategic risks and assurances within the HTA Strategic Risk Register attached to this paper at Annex A.

Background

4. The strategic risks are reviewed by the SMT monthly and the register updated. The strategic risk register that was updated at the beginning of January is at Annex A.

5. In line with the report to the previous ARAC meeting two risks remain amber rated: failure to manage regulatory expectations (risk three): and failure to utilise our capabilities (risk four).

6. The risk of failing to manage regulatory expectations (risk three) has seen no change to the overall rating. We continue to monitor perimeter issues for the HTA such as

opt out and Taphonomy as well as an increase in activity in relation to EU exit. Overall, this remains an area of increased activity for the HTA with an associated increase in delivery risks, to this point SMT do not feel that the overall risk has increased even with the increasing uncertainty relating to EU exit. We will continue to monitor this and the potential impact on regulatory expectations.

7. Risk 4, failure to utilise capabilities effectively, saw a slight uptick in December 2018 with the impact of the number of new starters and the effectiveness of the current induction programme being considered. Overall SMT did not consider there a need to increase the residual risk scoring.

8. In December 2018 SMT formulated a new risk, failure to achieve the benefits of the organisation transformation programme. Although we consider the pre mitigated impact to be high we score the likelihood at present as low – we still await formal sign off of our submitted business case from DHSC and therefore the programme cannot commence.

9. SMT is content that the strategic risk register is complete and that the planned actions to mitigate the risks to the levels reported are taking place.

HTA Strategic Risk Register
January 2019

Overview: Risks reflect the strategy for 2018 - 2021. Our highest risks are the failure to manage expectations of regulation, which reflects the fast-pace of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively which is currently affected by recent staff changes.
Other notable risks: Uncertainty posed by EU Exit, which is largely dependent on outcomes of the ongoing negotiations and resource dedicated to 'no-deal' planning which impacts on other work. Dedicating resource required to produce a Code of Practice for opt-out consent in England.
Recruitment for Regulation Managers has been successful with only one post vacant. All appointees have now taken up post. A number of more recently recruited Regulation Managers are now signed off to support and lead. This will increasingly have a mitigating impact on risks 1 and 4. Recruitment to the Head of Planning and Performance (previously Head of Operations) post has been successful and the appointee has started in post.
Further funding has been secured which will enable us to expedite key pieces of work, however this does create challenges which will affect risks 1 and 4.

Risk	*Nov 2018*	*Dec 2018*	*Jan 2019*	*Comments*
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)	→	→	→	*A good regulatory framework and processes are in place and continuous improvement is planned. It is important to identify changes and remain agile to adapt to these. A number of new Regulation Managers have increased the organisation's capacity and strengthened our regulatory capability. Recent recruitment has resulted in all but one Regulation Manager posts being filled, that vacancy having only arisen with effect from 1st January 2019.* *Recruitment for other vacancies is ongoing and despite seeing high levels of candidate drop out at interview stage, we have been successful in our recent recruit rounds so that, for example, our new Transplant Officer will take up post shortly before the departing Transplant Officer leaves. The development of a revised induction programme for RMs is progressing well but a review of Standard Operating Procedures is required in order to achieve consistency with consistent training in up to date practice.* *We recognise that there has been an issue with the speed at which new RMs are being inducted which is related to the pressure on existing staff who not only maintain BAU but are involved in other projects. We are actively working to address this and have*
2 - Failure to manage an incident (Delivery, Development and Deployment)	→	→	→	*Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 2016/17.* *The CIP was utilised to manage a building power outage during March 2018 and a regulatory issue in April 2018. Lessons learnt papers was discussed at ARAC, but the incidents were managed well.* *We are aware that if there is a 'no deal' EU Exit, this could affect our ability to respond or regulate effectively. We feel the plans in place are adequate.*
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)	→	→	→	*We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but which may adversely impact on public confidence is challenging. The number of perimeter issue shows no sign of decreasing. These issues and the planning for EU exit continue to occupy regulatory resource.* *We are conscious that we have staff operating in the frontline who may be challenged about issues beyond our control, which would be heightened in a 'no-deal' EU Exit.*
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	→	↑	→	*We continue to be in a positon to use the skills of our newer recruits more fully.* *Recruitment to RM posts has been successful, but not without salary pressure. Other roles have been harder to fill as a result of salary and T&C differences with other organisations. Workload and pressure continue to be monitored closely by the management team and the actions agreed as a result of the staff survey are now being implemented. We achieved our planned position relating to GDPR by the 25 May 2018 implementation date and have an initial defensible position. We have a plan that would allow for improved compliance by the end of March 2019 but delivering this may require trade offs with front line regulatory activity.* *We recognise that securing further funding creates pressure to spend it within the remaining time. Delivery could be at risk where we do not have sufficient staff resource to deliver any additional pieces of work that extra funding has given. We note that there is further work to be done on our induction processes which requires more people resource than is easliy available.* *DHSC has introduced spending controls which could impact on future delivery.*
5 - Insufficient, or ineffective management of, financial resources (Deployment b)	→	→	→	*Although we have seen a small decline in licence renewal it does not present a material challenge to achieving financial balance this year. Our April invoice run has been conducted and we will continue to monitor debtor levels and for any further changes to licence numbers.* *Funding secured to cover our increasing capital costs. This will impact on our ability to spend the cash received and we are therefore mindful that there is a risk of not spending the funds due to the level of effort/resource required to scope what is needed.* *DHSC spend control in place Q3 onwards, potentially could impact on future years*
6 - Failure to achieve the benefits of the organisational transformation programme (Development objectives a-d)	N/a	→	→	*This is a new risk for which we have begun to look at the outcomes and deliverables. The risk has been scored as high impact and low likelihood due to the proximity of the programme. The impact of 'high' recognises that aspects of the programme in particular IT related could have significant impact on the business should things go wrong.* *No change.*

Strategic Objectives

Delivery – to deliver the right mix of activity to main public and professional confidence
a) To deliver a right-touch program of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety;
b) To deliver effective regulation of living donation;
c) To provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;
d) To be consistent and transparent in our decision making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards;
e) To inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them, and influence them in matters that are important to us;
f) To maintain our strategic relationships with other regulators operating in the health sector

Development – to make the right investment in development to continuously improve delivery
a) To use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
b) To make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;
c) To provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements;
d) To develop and blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

Deployment – to make the most effective use of our people and resources in pursuit of our goals
a) To manage and develop our people in line with the HTA's People Strategy;
b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money;
c) To provide a suitable working environment and effective business technology, with due regard for data protection and information security;

Risks are assessed by using the grid below

Risk scoring matrix						
Impact	5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Risk Score = Impact x Likelihood		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
		Likelihood				

Lines of defence are:
1 - Embedded in the business operation
2 - Corporate oversight functions
3 - Independent of the HTA

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L							
1	***Failure to regulate in a manner that maintains public safety and confidence and is appropriate*** ***(Risk to Delivery objectives a-d & f Development objectives a-d)*** *Risk Owner:* ***Allan Marriott-Smith***	***Causes*** • *Failure to identify regulatory non-compliance* • *Regulation is not transparent, accountable, proportionate, consistent and targeted* • *Regulation is not sufficiently agile to respond to changes in sectors* • *Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)).* • *Inadequate adherence to agreed policies and procedures in particular in relation to decision making* • *Poor quality or out of date policies and procedures* • *Failure to identify new and emerging issues within HTA remit* • *Failure to properly account for Better Regulation* • *Insufficient funding in regulated sectors* • *Risk based approach to implementing Import and Coding regulations ahead of 31 March 2018 deadline* • *Failure to deal with regulatory consequences of EU exit* ***Effects*** • *Loss of public confidence* • *Compromises to patient safety* • *Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance* • *Reputational damage*	*5*	*4*	*Ongoing*	**Regulatory model**	**5**	**1**		1	2	3			
						HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model					X		Preventative	Authority developed and approved the HTA Strategy	HTA Strategy published in April
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory report made in November 2018
						Annual scheduled review of Strategy				X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in September 2018
						Approved HTA Business Plan 2018/19 identifies a balanced programme of regulatory activity and continuous improvement				X	X	X	Preventative	Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department	HTA Business Plan to be published in April and approved by the Department of Health
						Quality management systems									
						HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model				X			Preventative/ Monitoring	Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates	Management are aware of limitations in the QMS and have further work ongoing in 2018/19 to address these
						People									
						Adherence to the HTA People Strategy				X			Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made atNovember 2018 Authority meeting
						Training and development of professional competence				X			Preventative	Annual PDPs, RM proposals to SMT	Regulation training plan agreed by SMT in June. Training records added onto Simply Personnel and monthly HR updates presented at SMT. The mid year PDP process has been completed.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas				X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy	Staffing levels and risks reported quarterly to the Authority
						Quality management systems									
						Internal audit of quality management system adequacy and adherence (HL) by March 2018						X	Monitoring/ Detective		
						EU Exit									
						Close liason with DHSC and contingency planning for a range of outcomes including no-deal									
						Use of existing regulatory model to manage the outcomes of 'no-deal'									
									Regulatory model					The following to be refined when controls in place	
									Delivery of Licensing and inspection review projects and outcomes of HA Risk and PM Development work to strengthen our regulatory model (HL) 2018/19	X			Preventative		
									Extension of reporting arrangements to adverse events in the Research sector (NH) Proposals developed in 2018/19				Preventative		
									Consideration of Import licenced establishment in HA inspection planning. Establishments assessed in order of existing risk profile and level of activity	X			Preventative		
									People						
									Fundamental review of the People Strategy by April 2019	X			Preventative		
									Other						
									Strengthening horizon scanning arrangements	X			Preventative		
									Embed Better Regulation initiatives in the regulatory model	X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
2	***Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:*** • ***relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)*** • ***caused by deficiency in the HTA's regulation or operation*** • ***where we need to regulate, such as with emergency mortuaries*** • ***that causes business continuity issues*** ***(Risk to all Delivery Development and Deployment objectives)*** *Risk owner:* ***Nicky Harrison***	***Cause*** • *Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)* • *Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)* • *Failure to work effectively with partners/other organisations* • *Breach of data security* • *IT failure or attack incident affecting access to HTA office* • *Consequences of 'no-deal' EU Exit affecting supply routes, staff availability or mutiple incidents* ***Effect*** • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	*5*	*3*	Future, should event occur	Filled identified business-critical roles	**3**	**2**		X			Preventative	Monthly reports to HTAMG	Last report December 2018
						Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff				X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Reviewed by ARAC October 2018
						Media handling policy and guidance in place, including regular media training for key staff & Members with relevant scenarios, to supplement media release and enquiries SOPs				X			Preventative	Policy reviewed annually, training specifications Reports on media issues in Delivery Report	Media policy to be reviewed.
						Accessible lines to take and key messages for likely scenarios				X			Preventative	Documented, incidents reported to Chair and in Delivery Report	Delivery report to Authority meeting November 2018
						Availability of legal advice				X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy				X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Policy reviewed by Authority July 2018
						Onward delegation scheme and decision making framework agreed by the Authority				X	X		Preventative	Standing Orders and Authority minutes	SO reviewed and agreed in 4 May 2017 (next review May 2019)
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory reports made in November 2018
						IT security controls and information risk management				X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - agenda item at ARAC June 2018
						Critical incident response plan regularly reviewed and tested				X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT	CIP was used to manager a power outage during March 2018 and a regulatory incident arising in April 2018
						Evaluate test exercise of incident and feedback to all staff.				X			Preventative		Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018
						EU exit plans in place								Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
3	**Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach** **(Risk to Delivery objective e, and Development c)** Risk Owner: **Hazel Lofty**	**Cause** **External factors** • No scheduled review of Human Tissue Act and associated regulations • Rapidly advancing life sciences • Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates • Proposed move to deemed consent for Organ donation within England • Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario **Matters which certain stakeholder groups believe require review** • Scope of relevant material e.g. waste products • Licensing requirements e.g. transplantation research • Regulation relating to child bone marrow donors • Issues raised by emergence of social media e.g. non-related donors • Strengthening of civil sanctions for non-compliance **Matters which stakeholders/public may expect to be inside regulatory scope** • Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure • Police holdings • Products of conception and fetal remains • Data generated from human tissue • Funeral directors • Forensic research facilities • Cryonics • Body stores / Taphonomy • Imported material • Clinical waste • **Other** • Inadequate stakeholder management **Effect** • Diminished professional confidence in the adequacy of the legislation • Reduced public confidence in regulation of matters relating to human tissue • Reputational damage	4	4	Ongoing	Log of issues known to the HTA with respect to the legislation to inform DH and manage messages	4	3			X		Monitoring	Ongoing log	Log in place and reviewed at HTAMG quarterly. New issues identified in causes and effects
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope				X			Preventative/ Detective	Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting)	Last stakeholder group meeting in October 2018 Public Authority meeting in July 2018
						Active management of issues raised by the media – including the development of the HTA position on issues				X			Preventative/ Detective	Quarterly reports to Authority on communication (including media) activities	Last report in November 2018 - satisfactory
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence					X		Monitoring	Quarterly Accountability meetings with DH	Full year accountability meeting in April 2018 - positive. Last quarterly meeting January 2019.
						Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance)				X			Preventative	Published guidance for particular issues (e.g. pregnancy remains, and shortly, cord blood)	Pregnancy remains guidance published March 2015 Cord blood guidance issued in March 2016 Cryopreservation information for public published September 2018
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge				X			Preventative	Duty and its uses understood by SMT and Chair	Letter to Minister re. import and consent requirements for public display
						Legal advice now gives a clearer view of our Schedule 2, s. 20 powers				X			Preventative	Legal advice to be followed	Legal advice September 2016
						Codes of practice and standards – provide greater clarity on matters inside and outside of regulatory scope were published **April 2017.** Circulation of principles within Code A to wider stakeholders was undertaken Quarter 3 2017/18				X			Preventative	Project management, monthly HTAMG updates, quarterly update in Delivery Report	Delivered Review of implementation ongoing; advice issued to PM sector in response to inspection findings Novermber 2018
						Partial implementation of triennial review recommendations **March 2017**				X			Preventative and remedial	Recommendations form part of business plan	Good progress, most complete with only benchmarking to be finalised
						Plan to develop and strengthen the relationship with DIs				X			Preventative	Outline plan agreed by HTAMG	On track
						Public research - gaining a better understanding of public confidence and the factors which impact it - **complete Q2 2017/18**				X			Preventative	Authority reviewed of key messages	Authority undertook review of headline messages at strategic awayday October 2017. Paper taken to Feb 2018 Authority meeting
						Proactive horizon scanning and development of policy in emerging/complex areas Project complete Q3 2017, now business as usual				X			Preventative	Project plan to go to HTAMG	Project plan presented to HTAMG Q2 2017/18 Horizon scanning map in use and reviewed quarterly by HTAMG Horizon scanning standard agenda item at all stakeholder group, TAG, HWG
									Deliver programme or work to improve relationships with licensed establishments	X			Preventative	Programme monitored by HTAMG	Programme underway Licensed establishment engagement programme established to inform work New ToR for internal group to agree focus for next business year

							Regular meetings with DHSC policy team to inform planning for EU Exit and plan in place, including for a 'no-deal' scenario	*x*			*Preventative*	*Meetings diarised and actions recorded. Internal EU Exit lead identified. Quarterly updates provided to Authority in Development report, and substantive paper at February 2019 meeting*	*On track, but uncertainty remains* *Technical notices published by DHSC on preparation for no-deal August 2018* *Operational readiness guidance published 31 December 2018*

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
4	**Failure to utilise people, data and business technology capabilities effectively** **(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)** Risk Owner: **Allan Marriott-Smith**	• ***Cause*** *Lack of knowledge about individuals' expertise* • *Poor job and organisational design resulting in skills being under used* • *Poor line management practices* • *Poor project management practices* • *Poor leadership from SMT and Heads* • *Data holdings poorly managed and under-exploited* • *Inadequate business technology or training in the technology available* • *Lack of ring-fenced resource for 'no-deal' EU Exit* ***Effect*** • *Poor deployment of staff leading to inefficient working* • *Disaffected staff* • *Increased turnover leading to loss of staff* • *Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed* • *Poor use of technology resulting in inefficient ways of working* • *Inadequate balance between serving Delivery and Development objectives*	5	4		**People**	4	4							
						Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle				X	X		Preventative/ Monitoring	QMS reminders as policies due for review. SMT review of all revised policies	Regular review cycle recommenced in late summer
						Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review) Standard objectives for all line managers				X	X		Preventative/ Monitoring	PDP guidance reviewed annually and approved by SMT, newly introduced countersigning officer check	Guidance issued April 2018. Mid year review guidance issued in September 2018 and completed in December.
						Regular review of HTA organisational structure and job descriptions				X	X		Preventative	Recruiting to the currently agreed organisational structure and approved job descriptions	Structural review completed in June 2018. Job descriptions reviewed as posts become vacant and recruitment to new vacant posts almost complete.
						Feedback from HTA people about work, management and leadership				X	X		Monitoring/ Detective	Staff survey, exit interviews, staff forum (attended by SMT Member and Head of HR)	Report of exit interview presented to Authority in September 2017 Staff Survey action plan in place March 2018 ARAC chair regularly discusses staff issues with chair of staff forum.
						Data									
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)				X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade roll out to be scheduled following completion of UAT
						Business technology									
						Staff training in key business systems				X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date				X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. Monthly operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2018
						HTAMG Development schedule to be part of monthly meetings throughout 2017/18				X			Preventative		
									People						
									Development of new People strategy and organisational structure in summer 2018	X			Preventative	Currently identifying opportunities to collaborate with others in the ALB sector to tap into these opportunities	NHSBT Training - Effective Line Manager one of suite of training days taken up (Aug-17 onwards)
									Data						
									GDPR project underway to ensure data is compliant with new regulations - GDPR deadline 25 May 2018	X			Preventative	GDPR delivery project	GDPR - achieved defensible position by May 2018. Action plan exists for full compliance by March 2019.
									Business technology						
									Identify refresher training and targeted software specific training needs.	X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
5	*Insufficient, or ineffective management of, financial resources* *(Risk to Deployment objective b* *Risk Owner:* *Richard Sydee*	***Cause*** • *Fee payers unable to pay licence fees* • *The number of licenced establishments changes, leading to reduced fee income* • *Management fail to set licence fees at a level that recover sufficient income to meet resource requirements* • *Failure to estimate resource required to meet our regulatory activity* • *Poor budget and/or cash-flow management* • *Unexpected increases in regulatory responsibilities* • *Unforeseeable price increases / reductions in GIA* ***Effect*** • *Payments to suppliers and/or staff delayed* • *Compensatory reductions in staff and other expenditure budgets* • *Increased licence fees* • *Requests for further public funding* • *Draw on reserves* *Leading to:* • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and non payment of fees*	*4*	*4*	Ongoing	Budget management framework to control and review spend and take early action	2	3		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Last review February 2017
						Financial projections, cash flow forecasting and monitoring				X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report November 2018
						Licence fee modelling							Preventative	Annual update to fees model	Update agreed by the Authority November 2018
						Rigorous debt recovery procedure				X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Last quarterly report November 2018
						Reserves policy and levels reserves				X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2018
						Delegation letters set out responsibilities				X	X		Preventative	Delegation letters issued annually	Issued in April 2018
						Prioritisation when work requirements change				X			Preventative	Agreed business plan, monthly HTAMG and SMT reports	Last HTAMG report December 2018
						Fees model provides cost/income information for planning				X			Preventative	Annual review of fees model, reported to SMT and Authority	Update to be agreed by the Authority November 2017.
						Annual external audit				X			Detective	NAO report annually	Last report in June 2018 - clean opinion
									Monitoring of income and expenditure (RS) **Ongoing**			X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report November 2018
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**	X	X		Detective	Quarterly Finance Directors and Accountability meetings	Last FDs meeting Nov 2017

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L							
6	***Failure to achieve the benefits of the organisational transformation programme*** ***(Development objectives a-d)*** ***Risk owner*** ***Allan Marriott-Smith***	***Causes*** • *Programme and project benefits poorly defined and understood* • *Inadequate programme and project governance arrangements* • *Poorly specified programme and projects* • *Insufficient programme, project and change management skills* • *Inadequate leadership of change* • *Inability to access the necessary skills required at a affordable cost* • *Lack of staff buy-in to change* • *Management and Head stretch of delivering transformation alongside business as usual and other development activity* • *Insufficient agility in (re)deploying people to change projects* • *Poorly specified procurement and inadequate contract management* • *Realisation of single points of failure for DDAT and People Strategy* ***Effects*** • *Wasted public money* • *Failure to achieve the central strategic intent of the Authority* • *Reputational damage* • *Unaffordable cost over run* • *Staff demotivation* • *Data remains under-utilised* • *Technology inadequate to meet future needs (cost, functionality)*	*5*	*4*			**5**	**1**		1	2	3			
						SMT experience of organisational change, programme and project management				X			Preventative		
						HTA approach to the management of change projects (underpinned by PRINCE2)				X			Preventative		
						A number of trained project managers among HTA staff				X			Preventative		
						Experience of procurement and contract management				X			Preventative		
						Existing mechanisms for engaging staff				X			Preventative		
						Well established corporate governance arrangements and financial controls					X		Monitoring		
						Agreement to a phased delivery approach to avoid all or nothing investment				X			Preventative		
									Seek external advice on programme design and governance	X			Preventative		
									Embed Benefits Realisation Management methodolgy within programme	X			Preventative		
									Introduce a Programme Maangement Office	X			Preventative		
									Authority approval to proceed at key checkpoints		X		Monitoring		
									Undertake a formal training needs analysis for the Programme and the HTA more widely	X			Preventative		
									Training plan to encompass project and change management and HTA approach	X			Preventative		
									Development of procurement plan to deliver the DDAT Strategy	X			Preventative		
									SROs identified for Programmme and individual projects	X			Preventative		
									Schedule a regular programme of staff engagement events	X			Preventative		
									Establish an external stakeholder communications and engagement plan	X			Preventative		
									Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		
									Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
									Appointment of extrernal critical friend to counter potential optimism bias			X	Preventative		

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HTA Human Tissue Authority

Paper

Date	12 February 2019	**Paper reference**	AUD 32-18
Agenda item	11	**Author**	Rob Watson/Amy Thomas

Update on the Oversight of Third Parties in the Human Application Sector

Purpose of paper

1. To provide the Committee with an update on the progress made towards achieving strengthened oversight of third parties in the Human Application Sector.

2. To provide assurances about future oversight of third parties.

Decision-making to date

3. This is an update to the paper presented at the October 2018 ARAC meeting (AUD (21/18)).

Action required

4. Members of the Committee are asked to note the contents of this paper and to provide comments on the outlined approach.

Background

5. Previous papers to the Committee have set out risks identified that relate to the HTA's oversight of licensable activities carried out under third party agreements (TPAs) in the HA sector.

6. Amongst the root causes, identified for these risks, were: process gaps in management and governance of TPA information; lack of visibility for outward facing information and inconsistencies in guidance; and, systems that did not lend themselves to active information oversight.

7. A previous update to the Committee set out actions taken to achieving a complete data set for licensable activities carried out under the terms of a third party agreement and identifying immediate concerns.

8. Since then, work has been carried out, and further work is ongoing, to implement the recommendations from the HA risk project. This includes measures to address the root causes described above and provide consistency in the HTA's approach to oversight of third party agreements.

Progress towards implementing the TPA-related recommendations from the HA risk project

Improvements to outward facing information on TPAs

9. The content of all the HTA's webpages relating to TPAs has been reviewed and, where needed, revised text has been drafted. These revisions will replace existing website content in quarter four.

10. Some older website content does not reflect the HTA's current position on the use of TPAs. These pages have been removed from the website as a temporary measure to allow for appropriate changes to be made.

11. A separate review is also underway to ensure that users of our website can easily find TPA-related information, including relevant forms and guidance. We intend to complete this work by the end of quarter four.

12. The January professional e-newsletter will include a reminder for establishments of the requirement for them to notify the HTA of new TPAs prior to the commencement of the proposed activities. Information will also be included about the current process for doing this.

Development of internal processes to assure consistency of oversight

13. A template has been developed to collect TPA information from establishments and the inspection scheduling standard operating procedure (SOP) has been updated to reflect the revised process. Amendments are currently being made to other relevant SOPs and templates, including those relating to the conduct of inspections, the recording of inspection evidence, report writing and change tickets.

14. Decision making criteria will be set out for Regulation Managers (RMs) to inform their review of third party agreements. These can be applied when assessing TPA information as part of a licence application/variation or through a site visit inspection.

15. Training will be given to relevant staff once the documents and revised processes have been finalised and approved. It is currently anticipated that this training will be delivered by the end of quarter four.

Maintaining data quality

16. TPA-related data from the 2017/18 annual activity data collection exercise has been reviewed and consolidated into a master spreadsheet. The information will be transposed into CRM following implementation of the CRM upgrade.

17. A process has been established to ensure this information is reviewed and updated as part of each inspection, as well as when new information on third parties is submitted by an establishment.

18. This process will involve the licensing team requesting up-to-date TPA information from establishments as part of the initial request for documents at the time of inspection scheduling. This information will be reviewed by RMs to ensure the master spreadsheet is accurate and to determine the scope of the inspection. The licensing team will update our records if needed and capture the decision whether or not to visit third parties as part of the inspection process.

Review of third parties through the inspection process

19. The majority of TPAs are reviewed during site-visit inspections. As set out in the previous update, RMs will continue to review activities relating to third parties as part of their site visits. The improvements to internal processes, set out above, will bring greater consistency to this process. Where an area of risk is identified this will result in a focussed review of this area of licensable activity.

20. The above approach was trialled during a recent inspection. Following a review of TPA-related information, past inspection reports and discussions with the DI, which identified an increase in the level of licensable activity at the third party and a four-year gap between inspections of the third party by the HTA, it was agreed between the lead inspector and the Head of Regulation for the HA sector that inspection should include a visit to the third party.

21. Four shortfalls (one major (cumulative) and three minor) were identified in relation to the practices at the third party. These related to the monitoring of areas used to store temperature-sensitive reagents, staff training, donor selection processes and data retention procedures. The establishment has put a corrective and preventative action plan in place to address each of the shortfalls identified.

Future development work relating to the oversight of TPAs

22. As part of wider work across the HTA relating the creation of more robust processes for risk-based inspections, we will consider how information about TPAs can be used to inform an establishment's risk score.

Human Tissue Authority Audit and Risk Assurance Committee

Resourcing the Authority's Digital Transformation project

SMT thought it important to note that from a communication perspective we are attempting to present the change as an organisational transformation programme which aims to generate benefits by smarter working, much of which will require digital transformation but also encompasses HR and estates/office move. The responses below focus on the aspects of the programme which are covered in the Digital, Data and Technology (DDAT) Strategy.

"Deep dive" for meeting on Tuesday 12th February 2019 – suggested areas of focus

1. Please outline the principal elements of SMT's vision for the digital transformation project.

The HTA vision of sustainable, agile and resilient will achieve stakeholder benefits if we are able to make the right investment in digital, data and technology. This investment will:

- *Allow stakeholders to provide data once, and for us to use this in more flexible ways;*
- *Make it easier for stakeholders to comply with our requirements through more modern systems and interfaces;*
- *Provide more reliable management information to better target those requiring regulatory intervention and reduce the burdens on those who don't;*
- *Provide better insight into developments and trends in our licensed sectors and use this to promote learning in these sectors;*
- *Build more sustainable approach to our technology, avoiding the famine of underinvestment followed by the feast of large scale upgrades because systems are reaching their end of life;*
- *Exploit open source technology where appropriate to reduce IT licence fees and upgrade costs;*
- *Allow us to develop a workforce which works remotely by design to reduce office space requirements, control wage costs and support the industrial strategy.*

In our business case to DHSC we set out the benefits in this way:

"The benefits to the HTA, and therefore its stakeholders, of this transformation programme are based around improvements to systems and processes that facilitate a more targeted, risk-based, approach to regulation. This will also lead to a streamlining of our interactions with the public and professionals ensuring the information needs of each audience is met in the most timely and appropriate manner. These fall in to three broad categories:

- *Planned data and information capture to enable us to continually update our understanding of the regulatory landscape and the profile of risk. This allows us to ensure we have capability in place to enable us to meet current and emerging demands across all aspects of regulatory activity*

- *Better regulation through:*

    - *Targeting resource to risk and improving the efficiency of regulatory activity.*

    - 'Right-touch' regulation, in which the burden on any particular sector or institution is proportionate to the risk and wider public benefit.

    - Developing a broader range of regulatory tools to achieve our desired outcomes, ideally, developing a segmentation model of our regulated institutions

    - Using data and behavioural insight to identify and trial how best to influence behaviour through a range of means, up to and including inspection.

- *Being innovative in our use of data and technology. Using data and intelligence to improve our understanding and targeting of risk through risk profiling. Developing a culture of data / evidence-based continuous improvement (focusing on delivery of desired regulatory outcomes).*

2. Please provide any high level project plans with timelines where available.

   An overview of the programme broken down into the envisioned work packages is provided for discussion.

   More detailed programme and individual project plans will be developed by the Programme Manager once they are in post.

3. What does SMT consider to be the highest priority elements of the project?

   In order to support our people, and ensure that we continue to provide efficient and effective regulation, the remote by design elements would be the highest priority. This includes:
   - *investment in telephony and video-conferencing to support remote working;*
   - *investment in an updated information governance framework which will underpin an intranet and electronic document management system; laying the foundation for a sustainable digital workplace.*

It should be noted that there are also external drivers for some of the work, e.g. The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018 which came into force last year. These Regulations will require us to comply with accessibility standards on our website by September 2020. Coupled with a need to upgrade the current website platform to ensure continued security post-2020, this would make a case for a more fundamental review of the HTA's website allowing us to use data and insights from our sectors and the public to target content and architecture more appropriately.

4. What are the critical risks associated with delivering this project and how does management plan to mitigate them?

   The draft of the new strategic risk is attached with this response.

5. Given that much of the onus for delivering the project will rest on Dave Thomson, are there aspects of his current responsibilities which could be allocated to others during the project planning and implementation phases to free up capacity for him to lead on digital transformation?

   While we expect Dave to fulfil the senior user role for the projects within the portfolio we anticipate that there will be a number of other resources allocated either in-house or procured under contract to support delivery of the programme. This is where we would anticipate a significant proportion of the resource we are hoping to secure will be allocated.

   Critically we are currently assuming that we will appoint a Programme Office function to lead on the co-ordination of all digital and people projects.

   More generally, we are also assessing at SMT whether we should separate out Dave's operational responsibilities for data and information management from his responsibilities for business technology, as the demands of both have increased significantly in recent years, and will continue to do so.

   We have already increased the level of on-site support provided via our IT contract, both with the permanent on-site support (via a more experienced recruit) and short-term dedicated contractor provision to work on specific IT projects (e.g. the CRM upgrade). This is with the intention of building IT capability and capacity within the organisation, which will continue as we enter the transformation programme.

WP1 - Laying the foundations	**From now**
Define 'as-is' processes	
High level programme design	
Define Programme management and governance	
Define organisational approach to change	
Procure programme skills & build capability	
Define IT change management approach	
Define Cyber Security Strategy	
Define Information Governance Framework	
Develop policies to underpin framework	
Define 'to-be' processes & target operating model	
Define data strategy	
CRM upgrade deployment	
Review remote conference and meeting technologies to improve user experience	
Monitor laptop reliability to ensure good user experience	
Review Skype connectivity to improve user experience	
WP2 - Remote working by design	**tbc**
Pay framework	
Home workers contracts	
Plan for remote induction	
Initial cloud migration - what we have now	
Specify/plan/build intranet and collaboration tools	
Specify/plan/build electronic document and records management system	
WP 3 - Streamlining interactions - modern systems and interfaces	**tbc**
Specify/plan/build new HTA website	
Specify/plan/build new HTA portal	
WP 4 - Make better use of our data	**tbc**
Define data requirements - existing & new	
Configure systems to deliver data needs	

HTA Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	12 February 2018	**Paper reference**	AUD (34/18)
Agenda item	13	**Author** Morounke Akingbola	

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Policy and procedure updates

Purpose of paper

1. The purpose of this paper is to provide the Audit and Risk Assurance Committee (ARAC) an overview of any changes to the key policies and procedures that the Senior Management Team (SMT) have approved and to present the reviewed Reserves policy for ARAC approval.

Decision-making to date

2. The Anti-Fraud and Whistleblowing policies were reviewed by SMT in January 2019.

Action required

3. The Committee are asked to:

- Note schedule of policies (Annex A)
- note/comment on the Anti-Fraud and Whistleblowing policies (Annex B and C)

Background

4. All policies and procedures in the HTA are reviewed periodically, at least annually and sometimes more frequently. As a result, there is a culture of ongoing review and a commitment to continuous improvement.

Summary of finance policies and procedures

5. Annex A sets out the full range of finance policy and procedure documents approved by ARAC and SMT, together with their present status.

   Annex A Policies and Procedures Summary
   Annex B HTA-POL-050 Anti-Fraud Policy
   Annex C HTA-POL-017 Whistleblowing Policy

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Policy/Procedure & document reference	Purpose of policy/procedure	Status
Procurement Policy Doc Ref HTA/POL/027	Policy covers the authorisation process for purchases of different values	**Reviewed Sept-18** No changes
Financial Policies and Procedures Manual HTA/POL/028	This is a compendium of key finance policies in one document. There are links and cross-references to individual policies are made within this document.	**Reviewed in March-18**. Due to be updated pending the review of the Travel and Subsistence policy.
Budgetary Control Policy HTA/POL/031	Policy deals with the budget-setting process of the HTA and includes a draft timetable	**Reviewed in Jan-19** Review period changed from annual to every two years as process is standard every year.
Expenses Policy HTA/POL/032	Policy covers reimbursement of Travel, Subsistence and other expenses	**Reviewed Jan-19** Changes currently being shared with staff prior to its publication (April 2019). Key changes to use of private vehicles including mileage allowance. Driving for Work policy is new. Subsistence allowance changed to be more flexible.
Reserves Policy HTA/POL/049	Policy states the minimum level of cash reserves that the HTA should ideally keep as a contingency	**Reviewed Sept-18 and tabled** at ARAC Oct-18 meeting
Antifraud Policy HTA/POL/050	Policy covers definitions of fraud, responsibilities of HTA employees	**Reviewed Jan-19 and tabled** at ARAC Feb-19 meeting. Points 3 and 9 amended.

Whistle-blowing Policy HTA/POL/017	Policy covers procedure to be followed if they have concerns about improper behaviour	**Reviewed Jan-19 and tabled** at ARAC Feb-19 meeting – contacts updated; change to ARAC Chair and Staff Champion
Gifts and Hospitality Policy	Policy covers the procedure for receiving/declining gifts	**Reviewed Jan-19** No amendments made to policy, register tabled at ARAC Feb-19

HTA
Human Tissue Authority

Anti-fraud, Corruption and Bribery Policy

Version	15.3	**Date approved**	January 2019
Reference number	HTA/POL/50	**Next review due**	January 2020
Author(s)	Head of Finance	**Owner**	Director of Resources
Reviewed by	Director of Resources	**Distribution**	All staff
Approved by	SMT/Audit, Risk and Assurance Committee		

Revision history

Document each version or draft providing a simple audit trail to explain amendments.

Date	Version	Comments
April 2008	1.0	Draft for approval
June 2008	2.0	SMT approved
Feb 2009	2.1	Audit Committee Review
Aug 2011	2.2	Combined with whistleblowing policy
Nov 2011	2.3	Amended to standalone
Dec 2012	2.4	Reviewed by HoF
Feb 2014	2.5	Reviewed by HoF
Jan 2015	15.0	Reviewed by HoF
Jan 2016	15.1	Reviewed by HoF
Jan 2017	15.2	Reviewed by HoF
Jan 2018	15.2	Reviewed by HoF
Jan 2019	15.3	Reviewed by HoF/SMT

Description

1. This document sets out the HTA's policy on fraud, corruption and the response plan should fraud be detected or suspected.

Purpose

2. The anti-fraud policy aims to develop a culture across the HTA which raises awareness of the risks and consequences of fraud. This policy aims to help mitigate the risks of fraud and ineffective action.

3. It aims to promote good practice within the HTA through the following:

   a) zero tolerance to fraud;
   b) a culture in which bribery is never accepted;
   c) any allegations of fraud, anonymous or otherwise, will be investigated;
   d) consistent handling of cases without regard to position held or length of service;
   e) consideration of whether there have been failures of supervision. Where this has occurred, disciplinary action may be initiated against those responsible;
   f) any losses resulting from fraud will be recovered, if necessary through civil actions;
   g) publication of the anti-fraud policy on the HTA intranet site (IMPACT);
   h) all frauds will be reported to the Audit and Risk Assurance Committee.

4. This policy also sets out the responsibilities with regard to fraud prevention, what to do if you suspect fraud and the action that will be taken by management.

Introduction

5. The Human Tissue Authority (HTA) requires all staff at all times to act honestly and with integrity and to safeguard the public resources for which the HTA is responsible. The HTA is committed to ensuring that opportunities for fraud and corruption are reduced to the lowest reasonable level of risk. This paper sets out the policy on the control of fraud and suspected fraud within the HTA.

Scope

6. This policy applies to all the HTA's activities, wherever they are undertaken, to all individuals who work for the HTA, including contract staff, volunteers and freelancers and to individuals in a commercial relationship with the HTA e.g. the employees of suppliers. Awareness of the policy is made through the induction process.

7. The aim of the policy is to minimise the risk of any fraud being perpetrated against the HTA, thereby depriving the HTA of assets and resources and potentially damaging the HTA's reputation.

Definitions

What is Fraud?

8. The term is used to describe such acts as deception, bribery, forgery, extortion, corruption, theft, conspiracy, embezzlement, misappropriation, false representation, concealment of material facts and collusion.

9. For practical purposes fraud may be defined as the use of deception with the intention of obtaining an advantage, avoiding an obligation or causing loss to another party. Obviously fraud can be perpetrated by persons outside as well as inside an organisation. The criminal act is the attempt to deceive and attempted fraud is therefore treated as seriously as accomplished fraud.

10. The Fraud Act 2006 replaced parts of the Theft Acts of 1968 and 1978 which until then covered the offences of fraud. The 2006 Act introduced provisions for the general offence of fraud which broadened the interpretation of fraud. This is covered under 3 sections:-

    a) Section 2 – Fraud by false representation
    b) Section 3 – Fraud by failing to disclose information
    c) Section 4 – Fraud by abuse of position

11. False representation includes dishonestly making a false representation, and intending - by making the representation – to make a gain for oneself or another, or cause loss to another or to expose another to a risk of loss. A representation is false if it is untrue or misleading, and the person making it knows that it is, or might be, untrue or misleading.

12. A person is considered to have committed a fraud through abuse of position if he or she:

    a) occupies a position in which he/she is expected to safeguard, or not to act against, the financial interests of another person;
    b) dishonestly abuses that position; and
    c) Intends, by means of the abuse of that position to make a gain for himself or another, or to cause loss to another or to expose another to a risk of loss.

13. The Fraud Act 2006 also created new offences of:

    a) processing, making and supporting articles for use in fraud;

b) fraudulent trading;
c) obtaining services dishonestly.

14. The definition of fraud can cover a wide variety of misdemeanours and criminal culpability is not necessary for an act to be fraudulent, as the offence can be civil in nature.

15. Frauds can be attempted or carried out in a number of ways, including:

a) the theft of cash, cheques, equipment;
b) the falsification of travel and subsistence or other expense claims;
c) false claims for overtime (or flexible working);
d) irregularities in the tendering for, and execution and pricing of, supplies to the HTA by contractors of: property, goods, services, works and consultancy;
e) corruption, including the receipt of payment or other material advantage as an inducement to the award of contracts by the HTA.

16. Computer fraud is where information technology equipment has been used to manipulate programmes or data dishonestly (e.g. by altering, substituting or destroying records or creating spurious records), or where the use of an IT system was a material factor in the perpetration of fraud. Theft or fraudulent use of computer time and resources is included in this definition.

What is Bribery?

17. A bribe is an inducement or reward offered, promised or provided in order to gain any commercial, contractual, regulatory or personal advantage. The advantage sought or the inducement offered does not have to be financial or remunerative in nature, and may take the form of improper performance of an activity or function.

18. The Bribery Act 2010 includes the offences of:

a) Section 1 – bribing another person;
b) Section 2 – offences relating to being bribed.

19. Further guidance is at http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf

What is Corruption?

20. Corruption is defined as “The offering, giving, soliciting or acceptance of an inducement or reward which may influence the action of any person”. In addition “the failure to disclose an interest in order to gain financial or other pecuniary gain”.

Legal Basis

21. The HTA’s responsibilities in relation to fraud are set out in Annex 4.9 of Managing Public Money https://www.gov.uk/government/publications/managing-public-money.

Statement of Principles

22. The HTA will not accept any level of fraud or corruption; consequently any case will be promptly and thoroughly investigated and dealt with appropriately. Any member of staff found to be involved in theft, fraudulent action or conspiracy to defraud can expect to be dealt with in accordance with the agreed disciplinary procedures. Staff should draw attention to circumstances when they believe that there is improper behaviour by other HTA staff or external contacts of the HTA in accordance with the Whistleblowing Procedure. All matters will be dealt with in confidence and in strict accordance with the terms of the Public Interest Disclosure Act 1998, which protects the legitimate personal interests of staff.

Responsibilities

Chief Executive (CEO) (Accounting Officer)

23. The CEO as Accounting Officer is responsible for establishing and maintaining a sound system of internal control that supports the achievement of the HTA's policies, aims and objectives. The system of internal control is designed to respond to and manage the whole range of risks that the HTA faces. The system of internal control is based on an on-going process designed to identify the principal risks, to evaluate the nature and extent of those risks and to manage them effectively. Managing fraud risk is seen in the context of the management of this wider range of risks.

Director of Resources

24. Overall responsibility for managing the risk of fraud has been delegated to the Director of Resources. Their responsibilities include:

    a) Undertaking a regular review of the fraud risks associated with each of the key organisational objectives.
    b) Establishing an effective anti-fraud policy and fraud response plan, commensurate to the level of fraud risk identified.
    c) Assisting in the design of an effective control environment to prevent fraud.
    d) Establishing appropriate mechanisms for:
        i. Reporting fraud risk issues ;
        ii. reporting significant incidents of fraud or attempted fraud to the CEO;
        iii. Reporting to DHSC and Cabinet Office in accordance with Managing Public Money Annex 4.9;
        iv. Co-ordinating assurances about the effectiveness of the Anti-Fraud Policy to support the Annual Governance Statement;
        v. Liaising with the Finance Team and the Audit and Risk Assurance Committee;
        vi. Making sure that all staff are aware of the organisation's Anti-Fraud, Corruption and Bribery Policy and know what their responsibilities are in relation to combating fraud;
        vii. Ensuring that appropriate anti-fraud training is made available to staff as required;
        viii. Ensuring that appropriate action is taken to minimise the risk of previous frauds occurring in future.
    e) Ensuring that vigorous and prompt investigations are carried out if fraud occurs or is suspected; Taking appropriate legal and or/disciplinary action (in conjunction with HR) against perpetrators of fraud.
    f) In conjunction with HR, taking appropriate disciplinary action against supervisors where supervisory failures have contributed to the commission of fraud.

g) In conjunction with HR, taking appropriate disciplinary action against staff who knowingly fail to report fraud.
h) Taking appropriate action to recover assets.

Line Managers

25. The prevention and detection of fraud lies primarily with Line Managers as they are responsible for many of the processes and controls operated by the HTA. In particular they are responsible for:

a) Ensuring that an adequate system of internal control exists within their areas of responsibility and that controls operate effectively.
b) Preventing and detecting fraud as far as possible.
c) Assessing the types of risk involved in the operations for which they are responsible.
d) Reviewing regularly and testing the control systems for which they are responsible.
e) Ensuring that controls are being complied with and their systems continue to operate effectively, (this is key as most frauds occur because controls have not been enforced).
f) Implementing new controls to reduce the risk of similar fraud occurring where frauds have taken place.

Internal Audit

26. The prevention and detection of fraud within the HTA is a management and staff responsibility. However, Internal Audit can assist by:

a) Delivering an opinion to the CEO and the Authority on the adequacy of arrangements for managing the risk of fraud and advising the HTA on how to promote an anti-fraud culture.
b) Assisting in the deterrence and prevention of fraud by examining and evaluating the effectiveness of control commensurate with the extent of the potential exposure/risk in the various areas of the HTA's operations.
c) Ensuring that management has reviewed its risk exposures and identified the possibility of fraud as a business risk.

The DHSC Anti-Fraud Unit

27. The services of the DHSC Anti-Fraud Unit are available to the HTA on request. The unit provides advice, training about fraud prevention and investigation services. The Director of Resources or the Chief Executive will make the decision whether to call on this unit.

Staff

28. Every member of staff is responsible for:

a) Acting with propriety in the use of HTA's resources and the handling and use of HTA funds whether they are involved with cash, receipts, payments, stock or dealing with contractors and suppliers.
b) Conducting themselves in accordance with the seven principles of public life set out in the first report of the Nolan Committee "Standards in Public Life". They are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership.
c) Being alert to the possibility that unusual events or transactions could be indicators of fraud.
d) Alerting their line manager when they believe the opportunity for fraud exists e.g. because of poor procedures or lack of effective oversight.
e) Reporting immediately, in accordance with the Fraud Response Plan (Appendix 1) and Whistleblowing policy, if they suspect that a fraud has been committed or see any suspicious acts or events.
f) Cooperating fully with whoever is conducting internal checks or reviews or fraud investigations.

Procedures

29. The HTA has a Fraud Response Plan (Appendix 1) that sets out how to report suspicions and how investigations will be conducted and concluded.

Breach of the Policy

30. The HTA views fraud **EXTREMELY SERIOUSLY**. After proper investigation, the HTA will take legal and/or disciplinary action in all cases where it is considered appropriate. Where a case is referred to the police, the HTA will co-operate fully with police enquiries and these may result in the offender(s) being prosecuted. In all cases the HTA will seek to recover assets where it can.

31. The consequences of breaching the Anti-Fraud Policy are set out in more detail in the Fraud Response Plan (Appendix 1).

Deterrence

32. There are a number of ways in which we deter potential fraudsters from committing or attempting fraudulent or corrupt acts, whether they are inside or outside of the HTA, and these include:

    a) Publicising the fact that the Authority is firmly set against fraud and corruption at every appropriate opportunity.
    b) Acting robustly and decisively when fraud and corruption is suspected.
    c) Prosecution of offenders.

d) Taking action to effect maximum recovery for the HTA.
e) Having sound internal control systems, that still allow for innovation and efficiency, but at the same time minimising the opportunity for fraud and corruption.

Review

33. The Anti-Fraud, Corruption and Bribery Policy will be reviewed every year and after any occasion of fraud has been identified.

Appendices

1. Fraud Response Plan

2. Helpful dos and don’ts

Related documents

- Whistleblowing policy
- Bribery Act 2010
- Finance Procedures Manual
- Procurement and Tender Policy

APPENDIX 1

Fraud response plan

Introduction

1. The fraud response plan provides a checklist of actions and a guide to follow in the event that fraud is suspected. Its purpose is to define authority levels, responsibilities for action and reporting lines in the event of suspected fraud, theft or other irregularity. It covers:

   a) notifying suspected fraud;
   b) the investigation process;
   c) liaison with police and external audit;
   d) initiation of recovery action;
   e) reporting process;
   f) communication with the Audit and Risk Assurance Committee.

Notifying suspected fraud

2. It is important that all staff are able to report their concerns without fear of reprisal or victimisation and are aware of the means to do so. The Public Interest Disclosure Act 1998 (the "Whistleblowers Act") provides appropriate protection for those who voice genuine and legitimate concerns through the proper channels. More details are set out in Appendix 3.

3. In the first instance, any suspicion of fraud, theft or other irregularity should be reported, as a matter of urgency, to your line manager. If such action would be inappropriate, your concerns should be reported upwards to one of the following:

   a) your Head;
   b) your Director;
   c) Chief Executive;
   d) Audit and Risk Assurance Committee Chair;

4. Additionally, all concerns must be reported to the Director of Resources.

5. Every effort will be made to protect an informant's anonymity if requested. However, the HTA will always encourage individuals to be identified to add more validity to the accusations and allow further investigations to be more effective. In certain circumstances, anonymity cannot be maintained. This will be advised to the informant prior to release of information.

6. If fraud is suspected of the Chief Executive or Director of Resources, notification must be made to the Audit and Risk Assurance Committee Chair who will use suitable discretion and coordinate all activities in accordance with this response plan, appointing an investigator to act on their behalf.

7. If fraud by an Authority Member is suspected, it should be reported to the Chief Executive and the Director of Resources who must report it to the Chair to investigate. If fraud by the Chair is suspected, it should be reported to the Chief Executive and Director of Resources who must report it to the Chair of the Audit and Risk Assurance Committee to investigate.

The investigation process

8. Suspected fraud must be investigated in an independent, open-minded and professional manner with the aim of protecting the interests of both the HTA and the suspected individual(s). Suspicion must not be seen as guilt to be proven.

9. The investigation process will vary according to the circumstances of each case and will be determined by the Chief Executive in consultation with the Director of Resources. The process is likely to involve the DHSC Anti-Fraud Unit, who have expertise and resources to undertake investigations. An “Investigating Officer” will be appointed to take charge of the investigation on a day-to-day basis.

10. The Investigating Officer will appoint an investigating team. This may, if appropriate, comprise staff from within the Resources Directorate but may be supplemented by others from within the HTA or from outside.

11. Where initial investigations reveal that there are reasonable grounds for suspicion, and to facilitate the ongoing investigation, it may be appropriate to suspend an employee against whom an accusation has been made. This decision will be taken by the Chief Executive in consultation with the Director of Resources, the Head of HR and the Investigating Officer. Suspension should not be regarded as disciplinary action nor should it imply guilt. The process will follow the guidelines set out in HTA Disciplinary policy relating to such action.

12. It is important, from the outset, to ensure that evidence is not contaminated, lost or destroyed. The investigating team will therefore take immediate steps to secure physical assets, including computers and any records thereon, and all other potentially evidential documents. They will also ensure, in consultation with the Director of Resources, that appropriate controls are introduced in prevent further loss.

13. The Investigating Officer will ensure that a detailed record of the investigation is maintained. This should include chronological files recording details of all telephone

conversations, discussions, meetings and interviews (with whom, who else was present and who said what), details of documents reviewed, tests and analyses undertaken, the results and their significance. Everything should be recorded, irrespective of the apparent insignificance at the time.

14. All interviews will be concluded in a fair and proper manner and as rapidly as possible.

15. The findings of the investigation will be reported to the Chief Executive and Director of Resources. Having considered, with the Head of HR, the evidence obtained by the Investigating officer, the Chief Executive and Director of Resources will determine what further action (if any) should be taken.

Liaison with police & external audit

16. Some frauds will lend themselves to automatic reporting to the police (such as theft by a third party). For other frauds the Chief Executive, following consultation with the Director of Resources and the Investigating Officer will decide if and when to contact the police.

17. The Director of Resources will report suspected frauds to the police and external auditors at an appropriate time.

18. All staff will co-operate fully with any police or external audit enquiries, which may have to take precedence over any internal investigation or disciplinary process. However, wherever possible, teams will co-ordinate their enquiries to maximize the effective and efficient use of resources and information.

Initiation of recovery action

19. The HTA will take appropriate steps, including legal action if necessary, to recover any losses arising from fraud, theft or misconduct. This may include action against third parties involved in the fraud or whose negligent actions contributed to the fraud.

Reporting process

20. Throughout any investigation, the Investigating Officer will keep the Chief Executive and the Director of Resources informed of progress and any developments. These reports may be oral or in writing.

21. On completion of the investigation, the Investigating Officer will prepare a full written report to the Chief Executive and Director of Resources setting out:

    a) background as to how the investigation arose;
    b) what action was taken in response to the allegations;

c) the conduct of the investigation;
d) the facts that came to light and the evidence in support;
e) recommended action to take against any party where the allegations were proved (see policy on disciplinary action where staff are involved);
f) recommended action to take to recover any losses;
g) recommendations and / or action taken by management to reduce further exposure and to minimise any recurrence.

22. In order to provide a deterrent to other staff a brief and anonymous summary of the circumstances will be communicated to staff.

Communication with the Audit and Risk Assurance Committee

23. Irrespective of the amount involved, all cases of attempted, suspected or proven fraud must be reported to the Audit and Risk Assurance Committee by the Chief Executive or Director of Resources.

24. The Audit and Risk Assurance Committee will notify the Authority.

25. In addition, the Department requires returns of all losses arising from fraud together with details of:

a) all cases of fraud perpetrated within the HTA by members of its own staff, including cases where staff acted in collusion with outside parties;
b) all computer frauds against the HTA, whether perpetrated by staff or outside parties;
c) all cases of suspected or proven fraud by contractors arising in connection with contracts placed by the HTA for the supply of goods and services.

26. The Director of Resources is responsible for preparation and submission of fraud reports to the Audit and Risk Assurance Committee and the Department.

APPENDIX 2

Helpful dos and don’ts

DO	DON'T
Make a note of your concerns	**Be afraid of raising your concerns**
• Record all relevant details, such as the nature of your concern, the names of parties you believe to be involved, details of any telephone or other conversations with names dates and times and any witnesses. • Notes do not need to be overly formal, but should be timed, signed and dated. • Timeliness is most important. The longer you delay writing up, the greater the chances of recollections becoming distorted and the case being weakened	• The Public Interest Disclosure Act provides protection for employees who raise reasonably held concerns through the appropriate channels – whistleblowing. • You will not suffer discrimination or victimisation as a result of following these procedures and the matter will be treated sensitively. • Do not try to investigate the matter yourself, gather evidence or raise any issues with the person who is suspected of fraud.
Retain any evidence you may have	**Convey your concerns to anyone other than authorised persons**
• The quality of evidence is crucial and the more direct and tangible the evidence, the better the chances of an effective investigation.	• There may be a perfectly reasonable explanation for the events that give rise to your suspicion. Spreading unsubstantiated concerns may harm innocent persons.
Report your suspicions promptly	**Approach the person you suspect or try to investigate the matter yourself**
• In the first instance, report your suspicions to your line manager. If this action would be inappropriate, further guidance on disclosure can be found in the Fraud Response Plan and the Whistleblowing guidance. • Additionally, all concerns must be reported to the Director of Resources.	• There are special rules relating to the gathering of evidence for use in criminal cases. Any attempt to gather evidence by persons who are unfamiliar with these rules may destroy the case.

HTA
Human Tissue Authority

Whistleblowing Policy and Procedure

Version number	15.4	**Date approved**	January 2019
Reference	HTA-POL-17	**Next review due**	February 2020
Author(s)	Morounke Akingbola	**Owner**	Director of Resources
Reviewed by	Richard Sydee	**Distribution**	All staff
Approved by	SMT		

Revision history

Document each version or draft providing a simple audit trail to explain amendments.

Date	Version	Comments
April 2008	1.0	Draft for approval
June 2008	2.0	SMT approved
Feb 2009	2.1	Audit Committee Review
Aug 2011	2.2	Combined with whistleblowing policy
Nov 2011	2.3	Extracted to standalone
Dec 2012	2.4	Reviewed by Head of Finance
Feb 2014	2.5	Reviewed by Head of Finance
Jan 2015	15.0	Reviewed by Head of Finance
Jan 2016	15.1	Reviewed by Head of Finance
Nov 2017	15.2	Reviewed by Head of Finance
Jan 2018	15.3	Updated by Head of Finance
Jan 2019	15.4	Reviewed by Head of Finance/SMT

Description

1. The Public Interest Disclosure Act 1998 (PIDA) protects employees against detrimental treatment or dismissal as a result of any disclosure by them of normally confidential information in the interests of the public. The HTA's whistleblowing policy and procedure explains how concerns should be raised by staff and is in line with the Act.

2. This policy aims to mitigate the risk of inappropriate treatment of whistle-blowers.

Purpose

3. In accordance with PIDA, this policy sets out a clear and fair procedure:

   a) that staff may use if they wish to make disclosures about the HTA that they feel are in the public interest; and
   b) which the HTA will use to investigate such disclosures.

4. This policy applies to all employees, permanent, fixed-term and any temporary/agency staff.

5. The policy does not form part of any employee's contract of employment. It may be revised or withdrawn at the HTA's absolute discretion and at any time.

6. Concerns that are raised about issues at other establishments should be handled under the relevant policy and SOP.

Introduction

7. The HTA is committed to high ethical standards and fosters an open culture.

8. Whistleblowing is when an individual reports suspected wrongdoing at work. This is also known as 'making a disclosure in the public interest'. Simply, it is raising concerns, usually acting from a feeling of fairness or ethics, rather than out of personal interest.

9. Whistleblowing is different to making a complaint or raising a grievance. Usually these actions are taken when the individual is personally affected. The HTA has separate procedures for these.

10. Whistleblowing is important to safeguard the effective delivery of public services, and to ensure value for money. It serves to protect and reassure individuals, and to maintain a healthy working culture and an efficient organisation.

11. The sections below provide guidance to staff on the procedures to follow if they have concerns about improper behaviour that might indicate fraud or have serious implications for the HTA.

Raising concerns

12. A member of staff who has concerns should initially raise the matter with his or her line manager or Director. A concern should always be raised as soon as the whistle-blower becomes aware of it and they should gather no further information at this point.

13. Types of improper behaviours include actions that:

    a) are illegal;
    b) are in breach of a professional code or are otherwise unethical;
    c) make improper use of HTA funds;
    d) make improper use of HTA assets or sensitive data;
    e) involve maladministration;
    f) cause harm to another member of staff, HTA users or the general public;
    g) undermine the HTA's functions or reputation;
    h) attempt to cover up such malpractice.

14. If a member of staff feels unable to raise the matter through their line manager they may do so through HR or their Director. If the Director is implicated the concerns should be raised with the CEO. This also applies if the member of staff is dissatisfied with the line manager's response to his or her concerns. The member of staff may seek the support of their trade union and choose to be accompanied by a trade union representative or work colleague at any stage of the procedure. Advice is also available from the charity Public Concern at Work.

15. When a member of staff continues to feel that there has not been a satisfactory response by HTA management or that there are compelling reasons that the matter cannot be raised with HTA management, he or she may contact one of the following people detailed at Annex A

    a) If staff feel that they cannot raise the matter with anyone associated with the HTA, then they may contact the sponsorship team at the **Department of Health and Social Care** (also at Annex A).

    b) HTA staff may also use the **Whistleblowing Helpline**, which offers free, confidential and anonymous advice to the health sector: http://wbhelpline.org.uk/ or People Concerns at Work whistle@protect-advice.org.uk formerly known as Public Concern at Work.

16. The National Audit Office (NAO) are a prescribed person to whom disclosures can be made in cases of concerns about the proper conduct of public business, value for money, fraud and corruption in relation to the provision of centrally-funded public services. Their whistleblowing helpline is 020 7798 7999. Further advice is on the NAO website at www.nao.org.uk/about_us/contact_us/whistleblowing__concerns.aspx.

17. Staff should not raise their concerns publically unless in all the circumstances it is reasonable to do so (such as they receive an inadequate response through the proper

channels). To do so may breach other legislation and leave an employee unprotected by PIDA.

Action on concerns

18. It is fundamentally important to the success of the “whistleblowing” arrangements that staff can have confidence that their concerns will be taken seriously and that their position at the HTA will not be prejudiced unfairly by their raising issues of improper conduct. Whistle blowers who have acted in good faith have guaranteed protection under the provisions of PIDA.

19. All staff are protected from victimisation, harassment or disciplinary action as a result of any disclosure, where the disclosure is made in good faith and is not made maliciously or for personal gain.

20. There will be no adverse repercussions for an employee or other individual who raises a genuine concern in good faith, whether or not such a concern is subsequently found to be justified. If any harassment, bullying or victimisation of such a whistle-blower arises, this will be regarded as a disciplinary matter.

21. Whistle blowers may wish their identity and or the information they provide to be treated confidentially. In some cases, this may be possible, although the nature of the matter may be such that the investigation cannot be made or will be restricted if this is the case. If concerns are raised anonymously, they will still be investigated, but this may restrict or prevent proper action.

22. As soon as a manager is made aware of a concern and he or she has checked that it is a matter where the interest of others or the organisation may be at risk, it must be reported upwards to the appropriate Head and the Director, as long as the Head and the Director is not the subject of the allegation. If so, the contacts in paragraph 15 should be used. The allegation must be reported upwards even if the matter is satisfactorily resolved by the manager who received the complaint. If necessary, the Head and Director will confirm the action to be taken and the likely timescales.

23. The member of staff who raised the issue must be given a report in writing of the outcome of the investigation. This report should be sufficiently detailed such that the member of staff has confidence that the investigation and any consequential actions were appropriate. If the investigations are lengthy, an interim oral report should be given to the member of staff to reassure him or her that appropriate action is being taken.

24. Consideration should be given to referring an allegation to internal audit, either to conduct the investigation or to endorse the outcome. This should be discussed with the Director responsible for that area and the Director of Resources who is the HTA’s principle point of contact with the internal auditors.

25. Raising a false allegation maliciously may lead to disciplinary action under the HTA’s Disciplinary Procedure.

26. The nature of any whistleblowing allegation and the results of any investigation should be reported to the Audit and Risk Assurance Committee in order for the Committee to consider the impact on the HTA.

ANNEX A

a) **Chief Executive**
Allan Marriott-Smith
020 7269 1901
allan.marriott-smith@hta.gov.uk

b) **Authority Chair**
William Horne
07866 371580
William.Horne@hta.gov.uk

c) **Audit and Risk Assurance Committee Chair (Board Champion)**
Amanda Gibbon
07944 102644
amandagibbon@waitrose.com

d) **Staff Champion**
Clare Wend-Hansen
0207 269 1953
Clare.wend-hansen@hta.gov.uuk

Department of Health and Social Care
e) Roger Wallis (DHSC Sponsor Unit)
0113 254 6091
Roger.Wallis@dhsc.gov.uk

People Concerns at Work
f) https://www.pcaw.org.uk/advice-line/

HTA Human Tissue Authority

Audit and Risk Assurance Committee paper

Date	12 February 2019	**Paper reference**	AUD (35/18)
Agenda item	15	**Author**	Richard Sydee

Protective Marking	OFFICIAL

HTA Gifts and Hospitality Register

Purpose of paper

1. To present the latest Gifts and Hospitality Register to the Committee

Decision-making to date

2. None

Action required

3. Review and comment on the register.

Register of Gifts / Hospitality Received and Provided

Version: HTAG0001
Feb-19

DIVISION / DEPARTMENT: HTA
FINANCIAL YEAR: 2017/18 - 2018/19

	Details of the Gift or Hospitality						Provider Details			Recipient Details	
Type	**Brief Description of Item**	**Reason for Gift or Hospitality**	**Date(s) of provision**	**Value of Item(s)**	**Location where Provided**	**Action on Gifts Received**	**Name of Person or Body**	**Contact Name**	**Relationship to Department**	**Name of Person(s) or Body**	**Contact Name**
Receipt	Bottle of Champagne	Leaving gift for Staff member	12/04/2017	£30	HTA Offices	Accepted, staff member allowed to retain as gift was deemed to of a personal nature	BCC	D Atha	IT services supplier	Jamie Munro	
Receipt	Lunch	Lunch paid for by one of our suppliers of legal advice during a meeting	12/06/2017	£15 each	Not disclosed	Hospitality refused	Blake Morgan	Eve Piffaretti	Legal supplier	Victoria Marshment Sarah Bedwell	
Receipt	Dinner and drinks reception	Stakeholder	27/09/2017	Unknown	Not provided	Declined	NHSBT Cardiff	Ian Trenholm	Licensee and stakeholder	Bill Horne	
Receipt	Financial payment £150/£250	Participation in survey	21/11/2017	£150/£250	Not provided	Declined	SIS International Research	Cedric Marin	Cold call	David Thomson	
Receipt	Decorative plaque	As a thankyou for hosting the delegation	27/11/2017	Unknown	HTA Offices	Accepted	Ghuizhou Medical University	Amy Li	Visiting Academics	Amy Thomas	
Receipt	2 1,2kg tins of Quality Street	Christmas gift for staff	05/12/2017	Less than £15	HTA Offices	Accepted, distributed to all staff	BCC	D Atha	IT services supplier	David Thomson	
Receipt	Cinema screening - Star Wars	Registration to an event	13/12/2017	Less than £20	Not disclosed	Declined	Nutanix	Noor Ughratdar	None - sales call	David Thomson	
Receipt	Eye Masks, Biscuits, Cake	Thank you from	13/04/2018	£20	HTA Offices	Accepted	University of Tokyo	Dr Kayo Takashima	Visiting Research Fellow	Suet-Ping Wong, Julie Edgeworth, Adam Morris	Regulation, Comms Directorates
Receipt	Hamper	Non given	12/12/2018	Less than £20	HTA Offices	Accepted, distributed to all staff	BCC	D Atha	IT services supplier	D Thomson	
Receipt	Logo'd USB stick	Non given	21/12/2018	Less than £5	HTA Offices	Accepted, placed in stationery cupboard	Frontier Software	D Patel	Payroll Bureau	M Akingbola	
Receipt	Light refreshment	Provided for attendees at launch event	22/01/2019	Between £2-£3	Celtic Manor Resort	Accepted	Westfield Health British Transplant	Not given	Not given	Bill Horne	Authority Member